Exhibit B

IN THE CIRCUIT COURT OF COOK COUNTY
STATE OF ILLINOIS

ANDREA SANTIAGO,

Plaintiff,

v.

WALGREEN CO.;
WALGREENS BOOTS ALLIANCE, INC.;
BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.;
BOEHRINGER INGELHEIM CORPORATION;
BOEHRINGER INGELHEIM USA CORPORATION;
GLAXOSMITHKLINE, LLC;
GLAXOSMITHKLINE HOLDINGS (AMERICAS), INC.;
PFIZER, INC.; and
JOHN DOES 1-100 INCLUSIVE,

Defendants.

Case No.: 2023L007883

JURY TRIAL DEMANDED ON ALL COUNTS

PERSONAL INJURY

COMPLAINT

COMES NOW, Plaintiff, ANDREA SANTIAGO, through the undersigned counsel, and brings this action for personal injuries against Defendants, and alleges as follows:

INTRODUCTION

1. Zantac is the branded name for ranitidine, a "blockbuster" drug that was sold as a safe and effective antacid. But ranitidine transforms over time and under particular conditions into high levels of N-Nitrosodimethylamine ("NDMA"), a carcinogen that is as potent as it is dangerous. After almost four decades and billions of dollars of sales, ranitidine consumption has caused scores of consumers to develop cancer. Plaintiff brings this action for personal injuries resulting from Defendants' design, testing, marketing, labeling, packaging, handling, distribution,

storage and/or sale of brand-name Zantac products.

2. Until its 2020 recall by the Food and Drug Administration ("FDA"), ranitidine was a popular heartburn drug consumed by millions of people every day. Recent scientific studies, however, confirm what drug companies knew or should have known decades earlier: ingesting ranitidine exposes the consumer to unsafe and excessive amounts of NDMA.

3. NDMA is a well-known potent carcinogen. It was first discovered in the early 1900s as a byproduct of manufacturing rocket fuel. Today, its only use is to induce cancerous tumors in animals as part of laboratory experiments. Its only function is to cause cancer. It has no medicinal purpose whatsoever.

4. NDMA is not akin to other compounds that have a salutary effect at low levels and a negative effect with greater exposure. There is no recommended daily dose of NDMA. The ideal level of exposure is zero. Nonetheless, the FDA previously set an allowable daily limit of NDMA of 96 nanograms (ng) to minimize the risks posed by this dangerous molecule. Yet a single pill of ranitidine can contain quantities of NDMA that are hundreds, if not thousands, of times higher than the allowable limit.

5. Those recent revelations by the scientific community have caused widespread recalls of ranitidine both domestically and internationally. In fact, after numerous voluntary recalls, on April 1, 2020, the FDA ordered the immediate withdrawal of all ranitidine-containing products sold in the United States, citing unacceptable levels of NDMA accumulation.

6. The high levels of NDMA observed in ranitidine-containing products are a function of various factors. The ranitidine molecule internally degrades to form NDMA. The degradation of ranitidine into NDMA can increase over time under normal storage conditions, but more so with exposure to heat and/or humidity. Once in the body, ranitidine continues to degrade and can yield

increasing levels of NDMA in the human digestive system.

7. Zantac wreaked such widespread harm in large part because Defendant GlaxoSmithKline—the inventor of ranitidine through its predecessors—succumbed to a temptation that is all too familiar to pharmaceutical innovators: maximizing the profits of an incredibly lucrative, government-conferred monopoly.

8. To encourage pharmaceutical companies to invest in research and development ("R&D"), the U.S. legal and regulatory system offers drug companies who invent "new chemical entities" two powerful inducements. First, innovators obtain patent protection for their pharmaceutical compounds. Second, approved new drugs enjoy FDA exclusivity, irrespective of whether the molecule is protected by one or more issued patents. Taken together, these policies assure that a pharmaceutical innovator will receive the exclusive right, for a limited period of time, to sell its drug to the American public.

9. As a result, branded drug manufacturers have a strong—and too often perverse—incentive to sell as much product as they can during their exclusivity window. That is why brand-name manufacturers spend billions of dollars per year in sales and marketing efforts to push incremental sales of a brand-name drug. Where every $1 in new sales can produce upwards of $.90 in gross profit, staggering sales and marketing budgets are a very profitable investment. But while it makes sense for brand-name manufacturers to spend vast sums of money to develop and promote FDA-approved drugs, they have no economic or regulatory incentive to uncover and investigate developing risks posed by their products.

10. That problem is especially acute for bestselling, blockbuster drugs. Zantac is the brand that gave meaning to the term blockbuster pharmaceutical product, becoming the first drug ever to generate over $1 billion in annual sales. Zantac's success catapulted Glaxo ahead of its

previously larger rivals, fueling the market capitalization and corporate combinations that gave the company its current name: GlaxoSmithKline. It is little wonder Glaxo spared no expense to both get Zantac to market and to aggressively promote it to millions of consumers. Yet Glaxo did not part with a comparative pittance to investigate the obvious cancer risk posed by ranitidine. Turning a blind eye was far more profitable.

11. Ultimately, the law holds corporate entities responsible for the personal injuries caused by unsafe products, and in pharmaceutical liability actions, the entities that are responsible for developing, marketing, selling, packaging, distributing, and labeling the drugs. The civil justice system is the first, last, and only line of defense against the unchecked avarice that is a byproduct of a regulatory regime with the well-intentioned aim of bringing safe and effective medicines to market. Plaintiff seeks redress both for compensation for the horrific losses Plaintiff has suffered in the past and to strongly deter future misconduct.

THE PLAINTIFF'S CLAIM

12. From approximately 1998 through 2010, Plaintiff, ANDREA SANTIAGO, purchased and ingested over-the-counter ("OTC") name brand Zantac (hereinafter referred to as "Zantac") which was manufactured by each of the Brand Defendants to treat Plaintiff's symptoms of heartburn, acid indigestion, and other gastrointestinal conditions.

13. From approximately 1998 through 2010, Plaintiff purchased this Zantac from Walgreens.

14. The Zantac that Plaintiff purchased and ingested contained dangerous levels of the chemical ranitidine and N-Nitrosodimethylamine ("NDMA") and after ingestion some of the ranitidine created more NDMA in Plaintiff's body. The Zantac that Plaintiff purchased and ingested caused Plaintiff to develop breast cancer, which was diagnosed on or about March 1,

2009.

15. Plaintiff purchased Zantac at Walgreens in such quantities and with such frequency that the amount of Zantac that Plaintiff purchased at Walgreens was a substantial contributing cause of Plaintiff's cancer and the injuries alleged herein.

16. Plaintiff purchased and ingested Zantac that was manufactured by the Brand Defendants in such quantities and with such frequency that the amount of Zantac that Plaintiff purchased and ingested that was manufactured by each of the individual Brand Defendants was, from each individual manufacturer, a substantial contributing cause of Plaintiff's cancer and the injuries alleged herein.

17. The Zantac that Plaintiff purchased and ingested that was manufactured by the Brand Defendants and sold to Plaintiff by Walgreens was a direct and legal proximate cause of Plaintiff's cancer and the injuries alleged herein.

PARTIES

PLAINTIFF

18. Plaintiff is an individual and resident of Illinois.

19. Plaintiff began using Zantac in 1998 and continued to use it through 2010. Plaintiff obtained OTC Zantac at Walgreens pharmacies owned and operated by Defendants Walgreens Co. and Walgreens Boots Alliance, Inc.

20. During this time, Plaintiff was not aware that ingesting ranitidine-containing Zantac led to exposure to NDMA, or that ranitidine caused cancer.

21. Plaintiff was diagnosed with breast cancer on or about March 15, 2009 related to Plaintiff's ingestion of ranitidine-containing products. As a result of Plaintiff's cancer and subsequent treatment, Plaintiff has suffered significant bodily injury, pain and suffering, mental

anguish, disfigurement, embarrassment, inconvenience, loss of earnings and earning capacity, and have and will incur past and future medical expenses.

22. Based on prevailing scientific evidence, exposure to NDMA caused by consuming ranitidine can cause Plaintiff's type of cancer in humans.

23. Plaintiff's cancer was caused by ingesting Zantac Plaintiff obtained from Defendants Walgreens Co. and Walgreens Boots Alliance, Inc.'s pharmacies and stores.

DEFENDANTS

24. Defendants are entities that designed, manufactured, marketed, distributed, labeled, packaged, handled, stored, and/or sold ranitidine-containing Zantac.

Walgreens

25. Walgreen Co. and Walgreens Boots Alliance, Inc. derived substantial revenue from marketing, handling, distributing, storing, and selling Zantac products within each of the States and Territories of the United States, including in Cook County, Illinois.

26. Defendant Walgreen Co. is an Illinois corporation with its principal place of business located at 108 Wilmot Road, Deerfield, Illinois 60015. Walgreen Co. is a citizen of Illinois.

27. Defendant Walgreens Boots Alliance, Inc. is a Delaware corporation with its principal place of business located at 108 Wilmot Road, Deerfield, Illinois 60015. Walgreens Boots Alliance, Inc. is a citizen of Delaware and Illinois.

28. Walgreen Co. is a subsidiary of Walgreens Boots Alliance, Inc. Collectively, Walgreen Co. and Walgreens Boots Alliance, Inc. shall be referred to as "Walgreens" or "Walgreens Defendants."

29. Walgreens operates and derives substantial revenue from operating in excess of 100

retail pharmacies in Cook County, Illinois.

GlaxoSmithKline

30. Defendant GlaxoSmithKline LLC (also referred to herein as "GSK") is a Delaware limited liability company with its principal place of business located at Five Crescent Drive, Philadelphia, Pennsylvania, 19112. Defendant GlaxoSmithKline LLC's sole member is GlaxoSmithKline Holdings (Americas) Inc., a Delaware corporation with its principal place of business in that state. GlaxoSmithKline LLC is a citizen of Delaware.

31. Defendant GlaxoSmithKline LLC is a subsidiary of GlaxoSmithKline plc.

Pfizer

32. Pfizer, Inc. ("Pfizer") is a Delaware corporation with its principal place of business located at 235 East 42nd Street, New York, New York 10017.

Boehringer-Ingelheim

33. Boehringer Ingelheim Pharmaceuticals, Inc.,[1] is a Delaware corporation with its principal place of business located at 900 Ridgebury Road, Ridgefield, Connecticut 06877.

34. Boehringer Ingelheim Corporation is a Nevada corporation with its principal place of business located at 900 Ridgebury Road, Ridgefield, Connecticut 06877.

35. Boehringer Ingelheim USA Corporation is a Delaware corporation with its principal place of business located at 900 Ridgebury Rd., Ridgefield, Connecticut 06877.

JURISDICTION & VENUE

36. This Court has subject matter jurisdiction pursuant to 735 ILCS 5/2-209(b)(3-4), (c).

37. This Court has personal jurisdiction over Defendants insofar as Defendants are

[1] Defendants Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Corporation, and Boehringer Ingelheim USA Corporation shall be collectively referred to as "Boehringer Ingelheim" or "BI."

authorized and licensed to conduct business in Illinois, maintain and carry on systematic and continuous contacts in Illinois, and regularly transact business within Illinois.

38. Additionally, Defendants caused injury by acts and omissions in Illinois and caused injury in Illinois by acts and omissions outside Illinois while regularly doing and soliciting business, engaging in a persistent course of conduct, and receiving financial benefit and profits from goods used or consumed in Illinois.

39. At all relevant times, Defendants were present and doing business in Illinois, and should have expected that their acts would have consequences within the state of Illinois.

40. Walgreens is "at home" in Illinois because its principal place of business is located in Deerfield, Illinois.

41. Defendants GSK, Pfizer, and BI marketed and sold their various ranitidine-containing products throughout the United States, including in Illinois. Plaintiff ingested the various ranitidine-containing Zantac products manufactured, distributed, marketed, and sold by the Defendants, including in Illinois.

42. Venue is proper in Cook County because Walgreens operates and derives substantial revenue from operating in excess of 100 retail pharmacies in Cook County, and therefore is "doing business" in Cook County. 735 ILCS § 2-102(a); *Quigg v. Walgreen Co.*, 388 Ill.App.3d 696 (Ill. App. 2nd Dist. 2009). Further, venue is proper in Cook County because all Defendants conduct business within this County. 735 ILCS 5/2-101.

THE DEFECTIVE ZANTAC PRODUCT

43. At all relevant times during which Plaintiff purchased and ingested Zantac, the Zantac that Plaintiff purchased and ingested was manufactured and/or distributed and/or sold by one or more of GSK, Pfizer, and BI (hereinafter, the "Brand Defendants").

44. Each of the Brand Defendants owed a duty to Plaintiff and the public in general to assure that Zantac remained safe and free from any defects and/or unreasonable risks of danger to the consumers such as Plaintiff who would purchase and ingest Zantac. Each of the Brand Defendants breached their duties to Plaintiff and the public in general.

45. At all times relevant hereto each of the Defendants knew or should have known—as further explained in detail—that Zantac contained the active ingredient ranitidine. A derivative compound of ranitidine is N-Nitrosodimethylamine ("NDMA"), a well-known and dangerous carcinogen. As further explained herein, certain amounts of NDMA are inherent in the manufacture of Zantac, and then, once ranitidine is ingested, additional NDMA is created in greater amounts and in greater dangerous quantities in the stomach and intestines and in other parts of the human body. Hence, Zantac itself is a cancer-causing substance when used as intended by consumers such as Plaintiff.

46. At all relevant times hereto, the cancer-causing properties of Zantac were known to the Brand Defendants and Walgreens.

47. At all relevant times hereto, the cancer-causing properties of Zantac were unknown by ordinary consumers such as Plaintiff and were far beyond the reasonable expectations of the ordinary consumer such as Plaintiff. Zantac was at all relevant times hereto a defective product.

FACTUAL ALLEGATIONS

I. THE CREATION OF RANITIDINE-CONTAINING PRODUCTS AND THEIR INTRODUCTION TO THE MARKET

48. Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold ranitidine under the brand name Zantac.

49. Ranitidine belongs to a class of medications called histamine H_2-receptor antagonists (or H_2 blockers), which decrease the amount of acid produced by cells in the lining of

the stomach. Other drugs within this class include cimetidine (branded Tagamet), famotidine (Pepcid), and nizatidine (Axid).

50. GSK-predecessor Smith, Kline & French discovered and developed Tagamet, the first H_2 blocker and the prototypical histamine H_2 receptor antagonist from which the later members of the class were developed.

51. GSK[2] developed Zantac specifically in response to the success of cimetidine. Recognizing the extraordinary potential of having its own H_2 blocker in the burgeoning anti-ulcer market, GSK was all too willing to ensure its drug succeeded at all costs.

52. Allen & Hanburys Ltd., a then-subsidiary of Glaxo Laboratories Ltd., is credited with developing ranitidine and was awarded Patent No. 4,128,658 by the U.S. Patent and Trademark Office in December 1978, which covered the ranitidine molecule.

53. In 1983, the FDA granted 505(b) approval to Glaxo to sell Zantac, pursuant to the New Drug Application ("NDA") No. 18-703, and it quickly became GSK's most successful product—a "blockbuster." Indeed, Zantac became the first prescription drug in history to reach $1 billion in sales.

54. To accomplish this feat, GSK entered into a joint promotion agreement with Hoffmann-LaRoche, Inc. More salespersons drove more sales and blockbuster profits for GSK. GSK engaged in a multi-million-dollar promotional campaign throughout the United States, including in Cook County, Illinois.

55. In June of 1986, the FDA approved Zantac for maintenance therapy of duodenal ulcers and for treatment of patients with gastroesophageal reflux disease (GERD).

[2] GSK, as it's known today, was created through a series of mergers and acquisitions: In 1989, Smith, Kline & French merged with the Beecham Group to form SmithKline Beecham plc. In 1995, Glaxo merged with the Wellcome Foundation to become Glaxo Wellcome plc. In 2000, Glaxo Wellcome plc merged with SmithKline Beecham plc to form GlaxoSmithKline plc and GlaxoSmithKline LLC.

56. Between 1983 and 1994, GSK sought and obtained 505(b) approval for additional NDAs representing additional formulations of Zantac. These NDAs include 19-675, 20-095, and 20-251.

57. In December 1993, Glaxo (through Glaxo Wellcome plc) entered into a partnership agreement with Pfizer-predecessor company Warner-Lambert Co. to develop and market an OTC version of Zantac. In 1995, the FDA granted 505(b) approval to OTC Zantac 75 mg tablets through NDA 20-520. In 1998, the FDA granted 505(b) approval to OTC Zantac 75 mg effervescent tablets through NDA 20-745.

58. In 1998, GSK (Glaxo Wellcome plc) and Warner-Lambert Co. ended their partnership. As part of the separation, Warner-Lambert Co. retained control over the OTC NDA for Zantac and the Zantac trademark in the United States and Canada but was required to obtain approval from GSK prior to making any product or trademark improvements or changes. GSK retained rights to sell OTC Zantac outside of the United States and Canada and retained control over the Zantac trademark internationally.

59. In 2000, Pfizer acquired Warner-Lambert Co. Pfizer controlled the Zantac OTC NDAs until December 2006.

60. In October 2000, GSK sold to Pfizer the full rights to OTC Zantac in the United States and Canada pursuant to a divestiture and transfer agreement. As part of that agreement, GSK divested all domestic Zantac OTC assets to Pfizer, including all trademark rights. The agreement removed the restrictions on Pfizer's ability to seek product line extensions or the approval for higher doses of OTC Zantac.

61. GSK retained the right to exclusive use of the Zantac name for any prescription ranitidine-containing product in the United States.

62. In October 2003, Pfizer submitted NDA 21-698 for approval to market OTC Zantac 150 mg. The FDA granted 505(b) approval to NDA 21-698 on August 31, 2004.

63. During the time that Pfizer owned the rights to OTC Zantac, GSK continued to manufacture the product.

64. GSK continued marketing prescription Zantac in the United States until 2017 and still holds the NDAs for several prescription formulations of Zantac. GSK continued to maintain manufacturing and supply agreements relating to various formulations of both prescription and OTC Zantac. According to its recent annual report, GSK claims to have "discontinued making and selling prescription Zantac tablets in 2017 . . . in the U.S."[3]

65. All OTC Zantac formulations were submitted and approved as new NDAs under § 505(b) of the FDCA:

a. NDA 20-520 was approved by the FDA on December 19, 1995, and was issued to Glaxo Wellcome, Inc.;

b. NDA 20-745 was approved by the FDA on February 26, 1998, and was issued to Glaxo Wellcome, Inc.; and

c. NDA 21-698 was approved by the FDA on September 31, 2004, and was issued to Pfizer.

66. Subsequent formulations and variations of OTC Zantac were approved by the FDA as supplemental submissions under the heading of the above-listed NDAs.

II. NDMA IS A CARCINOGEN WHOSE DANGEROUS PROPERTIES ARE WELL ESTABLISHED.

67. According to the Environmental Protection Agency ("EPA"), "NDMA is a semivolatile organic chemical that forms in both industrial and natural processes."[4] It is one of

[3] GlaxoSmithKline, plc, *Annual Report* 37 (2019), https://www.gsk.com/media/5894/annual-report.pdf.

[4] U.S. Environmental Protection Agency, *Technical Fact Sheet – N-Nitroso-dimethylamine (NDMA)* (Nov. 2017), https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.

the simplest members of a class of N-nitrosamines, a family of potent carcinogens. Scientists have long recognized the dangers that NDMA poses to human health. A 1979 news article noted that "NDMA has caused cancer in nearly every laboratory animal tested so far."[5] NDMA is no longer produced or commercially used in the United States except for research. Its only use today is to cause cancer in laboratory animals.

68. Both the EPA and the International Agency for Research on Cancer ("IARC") classify NDMA as a probable human carcinogen.[6]

69. The American Conference of Governmental Industrial Hygienists classifies NDMA as a confirmed animal carcinogen.[7]

70. The Department of Health and Human Services ("DHHS") states that NDMA is reasonably anticipated to be a human carcinogen.[8] This classification is based upon DHHS's findings that NDMA caused tumors in numerous species of experimental animals, at several different tissue sites, and by several routes of exposure, with tumors occurring primarily in the liver, respiratory tract, kidney, and blood vessels.[9]

71. The FDA considers NDMA a carcinogenic impurity and chemical that "could cause

[5] Jane Brody, *Bottoms Up: Alcohol in Moderation Can Extend Life*, The Globe & Mail (CANADA) (Oct. 11, 1979); *see* Rudy Platiel, *Anger Grows as Officials Unable to Trace Poison in Reserve's Water*, The Globe & Mail (CANADA) (Jan. 6, 1990) (reporting that residents of Six Nations Indian Reserve "have been advised not to drink, cook or wash in the water because testing has found high levels of N-nitrosodimethylamine (NDMA), an industrial byproduct chemical that has been linked to cancer"); Kyrtopoulos et al, *DNA Adducts in Humans After Exposure to Methylating Agents*, 405 Mut. Res. 135 (1998) (noting that "chronic exposure of rats to very low doses of NDMA gives rise predominantly to liver tumors, including tumors of the liver cells (hepatocellular carcinomas), bile ducts, blood vessels and Kupffer cells").

[6] *See* EPA Technical Fact Sheet, *supra* note 6; Int'l Agency for Research on Cancer (IARC), *Summaries & Evaluations, N-NITROSODIMETHYLAMINE* (1978), http://www.inchem.org/documents/iarc/vol17/n-nitrosodimethylamine.html.

[7] *See* EPA Technical Fact Sheet, *supra* note 6.

[8] *Id.* at 3.

[9] *Id.*

cancer" in humans.[10] The FDA recognizes that NDMA is "known to be toxic."[11]

72. The World Health Organization states that there is "conclusive evidence that NDMA is a potent carcinogen" and that there is "clear evidence of carcinogenicity."[12] NDMA belongs to the so-called "cohort of concern" which is a group of highly potent mutagenic carcinogens that have been classified as probable human carcinogens.[13]

73. The EMA has referred to NDMA as "highly carcinogenic." It recommended that "primary attention with respect to risk for patients should be on these highly carcinogenic N-nitrosamines" (including NDMA), and categorized NDMA as "of highest concern with respect to mutagenic and carcinogenic potential."[14]

74. In 1989, the Agency for Toxic Substances and Disease Registry (ATSDR) stated that it is "reasonable to expect that exposure to NDMA by eating, drinking or breathing could cause cancer in humans" and that the "carcinogenicity of orally-administered NDMA has been demonstrated unequivocally in acute, intermediate and chronic durations studies" in animals and "it is important to recognize that this evidence also indicates that oral exposures of acute and intermediate duration are sufficient to induce cancer." Moreover, "hepatoxicity has been demonstrated in all animal species that have been tested and has been observed in humans who

[10] FDA Statement, Janet Woodcock, Director – Ctr. for Drug Evaluation & Research, *Statement Alerting Patients and Health Care Professionals of NDMA Found in Samples of Ranitidine* (Sept. 13, 2019), https://www.fda.gov/news-events/press-announcements/statement-alerting-patients-and-health-care-professionals-ndma-found-samples-ranitidine.

[11] Amneal_prod 1 _ 0000002938.

[12] World Health Org., *Guidelines for Drinking Water Quality, N-Nitrosodimethylamine (NDMA)* (3d ed. 2008), https://www.who.int/water_sanitation_health/dwq/chemicals/ndmasummary_2ndadd.pdf.

[13] International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk, M7(R1), March 2017; https://database.ich.org/sites/default/files/M7_R1_Guideline.pdf.

[14] Nitrosamines EMEA-H-A5(3)-1490 - Assessment Report (europa.eu) (June 25, 2020), https://www.ema.europa.eu/en/documents/referral/nitrosamines-emea-h-a53-1490-assessment-report_en.pdf.

were exposed to NDMA by ingestion or inhalation." [15]

75. As early as 1980, consumer products containing unsafe levels of NDMA and other nitrosamines have been recalled by manufacturers, either voluntarily or at the direction of the FDA.

76. Most recently, beginning in the summer of 2018, there have been recalls of several generic drugs used to treat high blood pressure and heart failure—Valsartan, Losartan, and Irbesartan—because the medications contained nitrosamine impurities that do not meet the FDA's safety standards.

77. This continued in 2020 when the FDA required recalls of numerous generic manufacturers' metformin.[16]

78. NDMA is a genotoxin that interacts with DNA and may subsequently induce mutations. Genotoxins are not considered to have a safe threshold or dose due to their ability to alter DNA.

79. The FDA has set an acceptable daily intake ("ADI") level for NDMA at 96 ng. That means that consumption of 96 ng of NDMA a day would increase the risk of developing cancer by 0.001% over the course of a lifetime. That risk increases as the level of NDMA exposure increases. However, any level above 96 ng is considered unacceptable.[17]

80. In studies examining carcinogenicity through oral administration, mice exposed to NDMA developed cancer in the kidney, bladder, liver, and lung. In comparable rat studies, cancers were observed in the liver, kidney, pancreas, and lung.

81. In other long-term animal studies in mice and rats utilizing different routes of

[15] ATSDR Toxicological Profile For N-Nitrosodimethylamine (December 1989), http://www.atsdr.cdc.gov/toxprofiles/tp141.pdf.

[16] https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-metformin.

[17] U.S. Food & Drug Admin., *FDA Updates and Press Announcements on Angiotensin II Receptor Blocker (ARB) Recalls (Valsartan, Losartan, and Irbesartan)* (Feb. 28, 2019), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan.

exposures—inhalation, subcutaneous injection, and intraperitoneal (abdomen injection)—cancer was observed in the lung, liver, kidney, nasal cavity, and stomach.

82. Numerous *in vitro* studies confirm that NDMA is a mutagen—causing genetic mutations in human and animal cells.

83. Overall, the animal data demonstrate that NDMA is carcinogenic in all animal species tested: mice; rats; Syrian golden, Chinese and European hamsters; guinea pigs; rabbits; ducks; mastomys; fish; newts; and frogs.

84. The EPA classified NDMA as a probable human carcinogen "based on the induction of tumors at multiple sites in different mammal species exposed to NDMA by various routes."[18]

85. Pursuant to EPA cancer guidelines, "tumors observed in animals are generally assumed to indicate that an agent may produce tumors in humans."[19]

86. In addition to the overwhelming animal data linking NDMA to cancer, there are numerous human epidemiological studies exploring the effects of dietary exposure to various cancers. These studies consistently show increased risks of various cancers.

87. In a 2000 epidemiological cohort study looking at occupational exposure of workers in the rubber industry, researchers observed significant increased risks for NDMA exposure for esophagus, oral cavity, and pharynx cancer.[20]

88. In a 2011 epidemiological cohort study looking at NDMA dietary exposure with 3,268 cases and a follow up of 11.4 years, researchers concluded that "[d]ietary NDMA intake was

[18] *Id.*

[19] *See* U.S. Envtl. Protection Agency, Risk Assessment Forum, *Guidelines for Carcinogen Risk Assessment* (Mar. 2005), https://www3.epa.gov/airtoxics/cancer_guidelines_final_3-25-05.pdf.

[20] Straif et al., *Exposure to High Concentrations of Nitrosamines and Cancer Mortality Among a Cohort of Rubber Workers*, 57 Occup. Envtl. Med 180–87 (2000).

significantly associated with increased cancer risk in men and women" for all cancers.[21]

89. NDMA is also known to be genotoxic – meaning, it can cause DNA damage in human cells. Indeed, multiple studies demonstrate that NDMA is genotoxic both *in vivo* and *in vitro*. However, recent studies have shown that the ability of NDMA to cause mutations in cells is affected by the presence of enzymes typically found in living humans, suggesting that "humans may be especially sensitive to the carcinogenicity of NDMA."[22]

90. In addition to studies demonstrating that NDMA directly causes cancer, research shows that exposure to NDMA (1) can exacerbate existing but dormant (*i.e.*, not malignant) tumor cells; (2) promote otherwise "initiated cancer cells" to develop into cancerous tumors; and (3) reduce the ability of the body to combat cancer as NDMA is immunosuppressive. Thus, in addition to NDMA being a direct cause of cancer itself, NDMA can also be a contributing factor to a cancer injury caused by some other source.

III. NDMA IS DISCOVERED IN RANITIDINE-CONTAINING PRODUCTS, LEADING TO MARKET WITHDRAWAL

91. Pharmacy and testing laboratory Valisure LLC and ValisureRX LLC (collectively, "Valisure") filed a Citizen Petition calling for the recall of all ranitidine-containing products due to detecting exceedingly high levels of NDMA when testing ranitidine pills using gas chromatography-mass spectrometry. FDA and European regulators started reviewing the safety of ranitidine with a specific focus on the presence of NDMA. This set off a cascade of recalls of ranitidine-containing products by GSK, other brand-name manufacturers, generic manufacturers, and retailers, including Walgreens.

92. The FDA's Director for Drug Evaluation and Research, Dr. Janet Woodcock,

[21] Loh et al., *N-nitroso Compounds and Cancer Incidence: The European Prospective Investigation into Cancer and Nutrition (EPIC)–Norfolk Study*, 93 Am. J. Clinical Nutrition 1053–61 (2011).
[22] World Health Org., *supra* note 14.

issued a statement warning that some ranitidine medicines may contain NDMA.

93. Defendants voluntarily recalled all ranitidine products and removed them from shelves.

94. The FDA ordered manufacturers of ranitidine to test their products and recommended using liquid chromatography with high-resolution mass spectrometer ("LC-HRMS") testing protocol, which "does not use elevated temperatures."

95. Defendant GSK voluntarily recalled all ranitidine-containing products internationally. As part of the recall, GSK publicly acknowledged that unacceptable levels of NDMA were discovered in Zantac.

96. The FDA announced the results of testing, finding unacceptable levels of NDMA in ranitidine-containing products, and requested that drug makers begin to voluntarily recall their ranitidine-containing products if the FDA or manufacturers discovered NDMA levels above the acceptable limits.

97. The FDA issued a statement notifying consumers who wished to continue taking ranitidine to consider limiting their intake of nitrite-containing foods, *e.g.*, processed meats and preservatives like sodium nitrite. This advice ***mirrored*** an admonition issued by Italian scientists in 1981 after finding that ranitidine reacted with nitrites *in vitro* to form toxic and mutagenic effects in bacteria. The prudent advice of Dr. de Flora published in October 1981 in *The Lancet* was to "avoid nitrosation as far as possible by, for example, suggesting a diet low in nitrates and nitrites, by asking patients not to take these at times close to (or with) meals or by giving inhibitors of nitrosation such as ascorbic acid."[23] If GSK had only heeded Dr. de Flora's advice in 1981, prior to the approval of NDA 18-703, millions of people might have avoided exposure to NDMA formed

[23] Silvio de Flora, *Cimetidine, Ranitidine and Their Mutagenic Nitroso Derivatives*, The Lancet, Oct. 31, 1981, at 993–94.

as a result of ranitidine's interaction with the human digestive system.

98. Research laboratory, Emery Pharma, submitted a Citizen Petition to the FDA, showing that the ranitidine molecule is heat-liable and under certain temperatures progressively accumulates NDMA.

99. Emery's Citizen Petition outlined its substantial concern that ranitidine is a time- and temperature-sensitive pharmaceutical product that develops NDMA when exposed to heat, a common occurrence during shipping, handling, and storage. Emery requested that the FDA issue a directive to manufacturers to clearly label ranitidine with a warning that "by-products that are probable carcinogens can be generated if exposed to heat." In addition to warning about this condition, Emery requested agency directives to manufacturers and distributors to ship ranitidine products in temperature-controlled vehicles.

100. In response, on April 1, 2020, the FDA recounted that a recall is an "effective methods [sic.] of removing or correcting defective FDA-regulated products . . . particularly when those products present a danger to health." The FDA sought the voluntary consent of manufacturers to accept the recall "to protect the public health from products that present a risk of injury." The FDA found that the recall of all ranitidine-containing products and a public warning of the recall was necessary because the "product being recalled presents a serious health risk." The FDA, therefore, sent Information Requests to all applicants and pending applicants of ranitidine-containing products "requesting a market withdrawal."

101. The FDA found its stability testing raised concerns that NDMA levels in some ranitidine-containing products stored at room temperature can increase with time to unacceptable levels. In the same vein, FDA testing revealed that higher NDMA levels were found as the products approached their expiration dates. The FDA's testing eroded the agency's confidence

that any ranitidine-containing product would remain stable through its labeled expiration date. Consequently, the FDA requested a market withdrawal of all ranitidine products. The FDA also announced to the public that the Agency's laboratory tests indicate that temperature and time contribute to an increase in NDMA levels in some ranitidine products. The FDA's decision to withdraw the drug rendered moot Emery's request for temperature-controlled shipping conditions.

102. The FDA's reaction was consistent with comparable regulatory action throughout the world. Before the FDA acted, over 43 different countries and jurisdictions restricted or banned ranitidine-containing products.

103. The European Medicines Agency ("EMA"), the European Union's equivalent to the FDA, through an Article 31 Referral, determined the sale of all ranitidine-containing products should be suspended. On April 30, 2020, the Human Medicines Committee of the EMA "has recommended the suspension of all ranitidine medicines in the EU due to the presence of low levels of an impurity called N-nitrosodimethylamine (NDMA)." The EMA recognizes NDMA as a probable human carcinogen and issued a "precautionary suspension of these medicines in the EU" because "NDMA has been found in several ranitidine medicines above levels considered acceptable, and there are unresolved questions about the source of the impurities."[24]

104. On September 17, 2020, after a ranitidine manufacturer requested that the EMA re-examine its decision and permit ranitidine to be marketed again in the EU, the EMA confirmed its prior recommendation to suspend all ranitidine medicines in the EU due to the presence of NDMA noting that it is a probable human carcinogen and that there is evidence that NDMA forms from

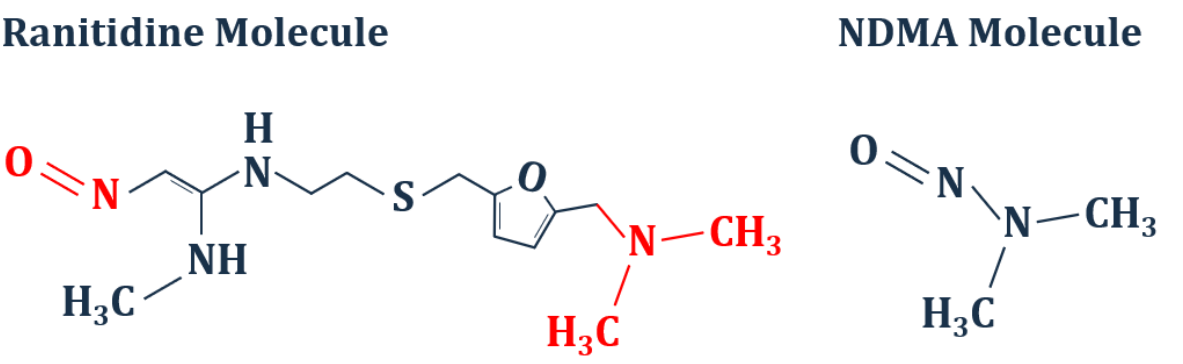
[24] Eur. Med. Agency, *Suspension of Ranitidine Medicines in the EU* (Apr. 30, 2020), https://www.ema.europa.eu/en/documents/referral/ranitidine-article-31-referral-suspension-ranitidine-medicines-eu_en.pdf.

the degradation of ranitidine itself with increasing levels seen over shelf life.[25]

IV. HOW RANITIDINE TRANSFORMS INTO NDMA

105. The ranitidine molecule itself contains the constituent molecules to form NDMA. *See* Figure 1.

Figure 1 – Diagram of Ranitidine & NDMA Molecules



106. The degradation occurs independently in two parts of the ranitidine molecule, with the products of the degradation combining to produce NDMA.

107. The formation of NDMA by the reaction of DMA and a nitroso source (such as a nitrite) is well characterized in the scientific literature and has been identified as a concern for contamination of the U.S. water supply.[26] Indeed, in 2003, alarming levels of NDMA in drinking water processed by wastewater-treatment plants were specifically linked to the presence of ranitidine.[27]

108. The high levels of NDMA observed in ranitidine-containing products are a function

[25] Eur. Med. Agency, EMA Confirms Recommendation to Suspend All Ranitidine Medicines in the EU (Nov. 24, 2020), https://www.ema.europa.eu/en/documents/referral/ranitidine-article-31-referral-ema-confirms-recommendation-suspend-all-ranitidine-medicines-eu_en.pdf.

[26] Ogawa et al., *Purification and Properties of a New Enzyme, NG, NG-dimethylarginine Dimethylaminohydrolase, from Rat Kidney*, 264 J. Bio. Chem. 17, 10205–209 (1989).

[27] Mitch et al., *N-Nitrosodimethylamine (NDMA) as a Drinking Water Contaminant: A Review*, 20 Env. Eng. Sci. 5, 389–404 (2003).

of various factors. The ranitidine molecule internally degrades to form NDMA. The degradation of ranitidine can increase over time under normal storage conditions, but more so with exposure to heat and/or humidity. Once in the body, ranitidine continues to degrade and can yield increasing levels of NDMA in the human digestive system, and when it interacts with nitrogenous products.

A. Formation of NDMA in the Environment of the Human Stomach

109. When the ranitidine molecule is exposed to the acidic environment of the stomach, particularly when accompanied by nitrites (a chemical commonly found in heartburn-inducing foods), the Nitroso molecule (0=N) and the DMA molecule (H_3C-N-CH_3) break off and reform as NDMA.

110. In 1981, Dr. Silvio de Flora, an Italian researcher from the University of Genoa, published the results of experiments he conducted on ranitidine in the well-known journal, *The Lancet*. When ranitidine was exposed to human gastric fluid in combination with nitrites, his experiment showed "toxic and mutagenic effects."[28] Dr. de Flora hypothesized that these mutagenic effects could have been caused by the "formation of more than one nitroso derivative [which includes NDMA] under our experimental conditions." *Id.* Dr. de Flora cautioned that, in the context of ranitidine ingestion, "it would seem prudent to … suggest[] a diet low in nitrates and nitrites, by asking patients not to take these at times close to (or with) meals."[29] *Id.*

111. GSK knew of Dr. de Flora's publication because, two weeks later, GSK responded in *The Lancet*, claiming that the levels of nitrite needed to induce the production of nitroso

[28] De Flora, *supra* note 25.

[29] This admonition came two years before the FDA approved Zantac in 1983. Notwithstanding, in 1998 GSK applied for and obtained an indication for OTC Zantac "[f]or the prevention of meal-induced heartburn at a dose of 75 mg taken 30 to 60 minutes prior to a meal." *See* Ctr. for Drug Eval. & Research, *Approval Package* (June 8, 1998), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/nda/98/20520s1_Zantac.pdf. GSK thus specifically invited patients to take Zantac shortly before eating heartburn-inducing food.

derivatives (*i.e.*, NDMA) were not likely to be experienced by people in the real world.[30]

112. This response reflects GSK's reputation for "adopting the most combative, scorched-earth positions in defense of its brands."[31] The company has no compunctions against distorting objective science to maintain its lucrative monopoly franchises, and its egregious conduct surrounding Zantac is not some isolated incident.

113. GSK endangered patient health while reaping billions of dollars in profits from Paxil, Wellbutrin, and Avandia. As we now know, the company was involved in covering up scientific data, offering illegal kickbacks to prescribing physicians, intimidating witnesses, and defrauding Medicare to profit from these medicines. In the wake of Congressional hearings into the company's outrageous misbehavior,[32] GSK's actions resulted in a criminal investigation and the then-largest guilty plea by a pharmaceutical company for fraud and failure to report safety data in the country's history.[33] There is currently an open investigation of GSK and Sanofi being conducted by the Department of Justice relating to the failure to disclose to the federal government information about the potential presence of NDMA in Zantac.[34]

114. GSK attended an FDA Advisory Committee in May 1982 where its representative testified and presented evidence relating to the safety of Zantac, including the potential for ranitidine to form nitrosamines. However, GSK failed to disclose its new evidence relating to ranitidine and the formation of a nitrosamine, specifically the formation of NDMA.

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[30] R. T., Brittain et al., *Safety of Ranitidine*, *The Lancet* 1119 (Nov. 14, 1981).

[31] Jim Edwards, *GSK's Alleged Coverup of Bad Avandia Data: A Snapshot of Its Poisonous Corporate Culture*, Moneywatch (July 13, 2010) https://www.cbsnews.com/news/gsks-alleged-coverup-of-bad-avandia-data-a-snapshot-of-its-poisonous-corporate-culture/.

[32] *Staff Report on GlaxoSmithKline and the Diabetes Drug Avandia*, Senate Comm. on Finance, 111th Cong.2d Sess. 1 (Comm. Print Jan. 2010).

[33] U.S. Dep't of Justice, *GlaxoSmithKline to Please Guilty and Pay $3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data* (July 2, 2012), https://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay-3-billion-resolve-fraud-allegations-and-failure-report.

[34] https://www.sanofi.com/-/media/Project/One-Sanofi-Web/Websites/Global/SanofiCOM/Home/en/investors/docs/2020_07_29_HY_financial_report_EN.pdf.

115. One month later, in June 1982, GSK submitted its draft Summary Basis of Approval and labeling for Zantac. Again, GSK failed to submit or otherwise disclose its new evidence relating to ranitidine and the formation of NMDA.

116. In its submission to the FDA, GSK discussed its findings from internal studies performed in 1980 that ranitidine formed a different nitrosamine, n-nitroso-nitrolic acid, a potent mutagen, but explained that these results had no "practical clinical significance"[35]:

> Although N-nitroso-nitrolic acid was a potent mutagen, it is not likely to be formed in the stomach of a patient ingesting ranitidine, as an unrealistically large amount of nitrite needs to be present to form and maintain the nitrosamine. For this reason, and also because ranitidine was not carcinogenic in life-span studies in rodents, the in vitro nitrosation of ranitidine to a mutagenic nitrosamine does not seem to have practical clinical significance.

117. In 1980—before Zantac was approved by the FDA—GSK conducted another study to examine, among other things, how long-term use of ranitidine could affect the levels of nitrite in the human stomach.[36] Remarkably, GSK admitted that ranitidine use caused the proliferation of bacteria in the human stomach that are known to convert nitrates to nitrites, which leads to elevated levels of nitrite in the stomach environment. GSK acknowledged this could increase the risk of forming nitrosamines and, in turn, cancer, but then dismissed this risk because people were allegedly only expected to use ranitidine-containing products for a short-term period:

[35] Excerpted from the Summary Basis of Approval submitted to the FDA to obtain approval of Zantac in the early 1980s. This document was obtained through a Freedom of Information Act request to the FDA.

[36] The results of this study are discussed in the Summary Basis of Approval, obtained from the FDA.

The importance of this finding is not clear. High levels of nitrite could react with certain organic compounds to form nitrosamines, which are known carcinogens. To date, however, neither ranitidine nor cimetidine have been carcinogenic in rodents, so the level of human risk cannot be estimated from animal studies. Ranitidine is recommended only for short-term use and carcinogenic risk, if any, should thus be minimized.

118. GSK knew—and indeed specifically admitted—that ranitidine could react with nitrite in the human stomach to form nitrosamines and, at the same time, that long-term use of ranitidine could lead to elevated levels of nitrite in the human stomach. GSK also knew but did not disclose that it had new evidence showing that NDMA was generated by ranitidine under certain conditions.

119. In response to Dr. de Flora's findings, in 1982, GSK conducted a clinical study specifically investigating gastric contents in human patients.[37] The study, in part, specifically measured the levels of N-Nitroso compounds in human gastric fluid. GSK indicated that there were no elevated levels, and even published the results of this study five years later, in 1987. The study, however, was flawed. It did not use gold-standard mass spectrometry to test for NDMA, but instead, used a process that could not measure N-nitrosamines efficiently. And worse, in the testing it did do, GSK refused to test gastric samples that contained ranitidine in them out of concern that samples with ranitidine would contain "high concentrations of N-nitroso compounds being recorded."[38] In other words, GSK intentionally engineered the study to exclude the very samples most likely to contain a dangerous carcinogen.

120. Given the above information that was disclosed relating to the nitrosation potential and formation of nitrosamines, it is shocking that GSK conducted an internal study to assess the

[37] Thomas et al., *Effects of One Year's Treatment with Ranitidine and of Truncal Vagotomy on Gastric Contents*, 6 Gut. Vol. 28, 726–38 (1987).
[38] *Id.*

formation of NDMA and found that ranitidine, when exposed to sodium nitrite, formed hundreds of thousands of nanograms of NDMA. The GSK study was never published or disclosed to the public.

121. In 1983, the same year GSK started marketing Zantac in the United States, seven researchers from the University of Genoa published a study discussing ranitidine and its genotoxic effects (ability to harm DNA).[39] The researchers concluded, "it appears that reaction of ranitidine with excess sodium nitrite under acid conditions gives rise to a nitroso-derivative (or derivatives) [like NDMA] capable of inducing DNA damage in mammalian cells." *Id.*

122. Then, again in 1983, Dr. de Flora, along with four other researchers, published their complete findings.[40] The results "confirm our preliminary findings on the formation of genotoxic derivatives from nitrite and ranitidine." Again, the authors noted that, "the widespread clinical use [of ranitidine] and the possibility of a long-term maintenance therapy suggest the prudent adoption of some simple measures, such as a diet low in nitrates and nitrites or the prescription of these anti-ulcer drugs at a suitable interval from meals." This admonition carries weight considering GSK's studies indicate that long-term ranitidine consumption, itself, leads to elevated levels of nitrites in the human gut.

123. The high instability of the ranitidine molecule was elucidated in scientific studies investigating ranitidine as a source of NDMA in drinking water and specific mechanisms for the breakdown of ranitidine were proposed.[41] These studies underscore the instability of the NDMA group on the ranitidine molecule and its ability to form NDMA in the environment of water-

[39] Maura et al., *DNA Damage Induced by Nitrosated Ranitidine in Cultured Mammalian Cells*, 18 Tox. Lttrs. 97–102 (1983).
[40] De Flora et al., *Genotoxicity of Nitrosated Ranitidine*, 4 Carcinogenesis 3, 255–60 (1983).
[41] Le Roux et al., *NDMA Formation by Chloramination of Ranitidine: Kinetics and Mechanism*, 46 Envtl. Sci. Tech. 20, 11095–103 (2012).

treatment plants that supply many U.S. cities with water.

124. In 2016, researchers at Stanford University conducted an experiment on healthy adult volunteers.[42] They measured the NDMA in the urine of healthy individuals over the course of 24 hours, administered one dose of ranitidine, and then measured the NDMA in the urine of the same individuals for another 24 hours. The study reported that on average, the level of NDMA increased by 400 times, to approximately 47,000 ng. The only change during that 24-hour period was the consumption of ranitidine. In the study, the scientists further explained that previous studies have indicated a high metabolic conversion rate of NDMA, meaning it will be processed by the human body. This study showed that ranitidine generates NDMA in the human body.

125. Valisure is an online pharmacy that also runs an analytical laboratory that is ISO 17025 accredited by the International Organization for Standardization ("ISO")—an accreditation recognizing the laboratories technical competence for regulatory purposes. Valisure's mission is to help ensure the safety, quality, and consistency of medications and supplements in the market. In response to rising concerns about counterfeit medications, generics, and overseas manufacturing, Valisure developed proprietary analytical technologies that it uses in addition to FDA standard assays to test every batch of every medication it dispenses.

126. In its Citizen's Petition to the FDA, Valisure disclosed as part of its testing of ranitidine-containing products that in every lot tested there were exceedingly high levels of NDMA. Valisure's ISO 17025 accredited laboratory used FDA recommended GC/MS headspace analysis method FY19-005-DPA for the determination of NDMA levels. As per the FDA protocol, this method was validated to a lower limit of detection of 25 ng. The results of Valisure's testing show levels of NDMA well above 2 million ng per 150 mg Zantac tablet, shown below in Table

[42] Zeng et al., *Oral intake of Ranitidine Increases Urinary Excretion of N-nitrosodimethylamine*, 37 Carcinogenesis 625–34 (2016).

1.

Table 1 – Ranitidine Samples Tested by Valisure Laboratory Using GC/MS Protocol		
150 mg Tablets or equivalent	**Lot #**	**NDMA per tablet (ng)**
Reference Powder	125619	2,472,531
Zantac, Brand OTC	18M498M	2,511,469
Zantac (mint), Brand OTC	18H546	2,834,798
Wal-Zan, Walgreens	79L800819A	2,444,046
Wal-Zan (mint), Walgreens	8ME2640	2,635,006
Ranitidine, Strides	77024060A	2,951,649

127. This testing by GC-MS demonstrates the instability of the ranitidine molecule and its propensity to break down under higher temperatures.

128. Valisure was concerned that the extremely high levels of NDMA observed in its testing were a product of the modest oven heating parameter of 130 °C in the FDA recommended GC/MS protocol. So Valisure developed a low temperature GC/MS method that could still detect NDMA but would only subject samples to 37 °C, the average temperature of the human body. This method was validated to a lower limit of detection of 100 ng.

129. Valisure tested ranitidine tablets by themselves and in conditions simulating the human stomach. Industry standard "Simulated Gastric Fluid" ("SGF": 50 mM potassium chloride, 85 mM hydrochloric acid adjusted to pH 1.2 with 1.25 g pepsin per liter) and "Simulated Intestinal Fluid" ("SIF": 50 mM potassium chloride, 50 mM potassium phosphate monobasic adjusted to pH 6.8 with hydrochloric acid and sodium hydroxide) were used alone and in combination with various concentrations of nitrite, which is commonly ingested in foods like processed meats and is elevated in the stomach by antacid drugs. The inclusion of nitrite in gastric fluid testing is commonplace and helps simulate the environment of a human stomach.

130. Indeed, ranitidine-containing products were specifically advertised to be used when consuming foods containing high levels of nitrates, such as tacos or pizza.[43]

131. The results of Valisure's tests on ranitidine tablets in biologically relevant conditions demonstrate significant NDMA formation under simulated gastric conditions with nitrite present (*see* Table 2).

Table 2 – Valisure Biologically Relevant Tests for NDMA Formation

Ranitidine Tablet Studies	**NDMA (ng/mL)**	**NDMA per tablet (ng)**
Tablet without Solvent	Not Detected	Not Detected
Tablet	Not Detected	Not Detected
Simulated Gastric Fluid ("SGF")	Not Detected	Not Detected
Simulated Intestinal Fluid ("SIF")	Not Detected	Not Detected
SGF with 10 mM Sodium Nitrite	Not Detected	Not Detected
SGF with 25 mM Sodium Nitrite	236	23,600
SGF with 50 mM Sodium Nitrite	3,045	304,500

132. Under biologically relevant conditions, when nitrites are present, high levels of NDMA are found in one dose of 150 mg ranitidine, ranging between 245 and 3,100 times above the FDA-allowable limit. One would need to smoke over 500 cigarettes to achieve the same levels of NDMA found in one dose of 150 mg ranitidine at the 25 nanogram level (over 7,000 for the 50 nanogram level).

133. Following the release of Valisure Citizen's Petition, the FDA conducted additional laboratory tests, which showed NDMA levels in all ranitidine samples it tested, including API and the finished drug, both tablets and syrup. The FDA developed simulated gastric fluid ("SGF") and simulated intestinal fluid ("SIF") models to use with the LC-MS testing method to estimate the

[43] *See, e.g.*, Zantac television commercial, *Family Taco Night*, https://www.ispot.tv/ad/dY7n/zantac-family-taco-night; Zantac television commercial, *Spicy*, https://youtu.be/jzS2kuB5_wg; Zantac television commercial, *Heartburn,* https://youtu.be/Z3QMwkSUlEg; Zantac television commercial, *Zantac Heartburn Challenge*, https://youtu.be/qvh9gyWqQns.

biological significance of *in vitro* findings. These models are intended to detect the formation of NDMA in systems that approximate the stomach and intestine.

134. When the scientific data is assessed overall, the literature demonstrates that the ingestion of ranitidine already containing NDMA combined with the presence of human-relevant levels of nitrite in the stomach—a substance that is commonly found in foods that induce heartburn and that is known to be elevated in people taking ranitidine for longer than a month—the ranitidine molecule transforms into more NDMA which would dramatically increase a person's risk of developing cancer.

B. Formation of NDMA in Other Organs of the Human Body

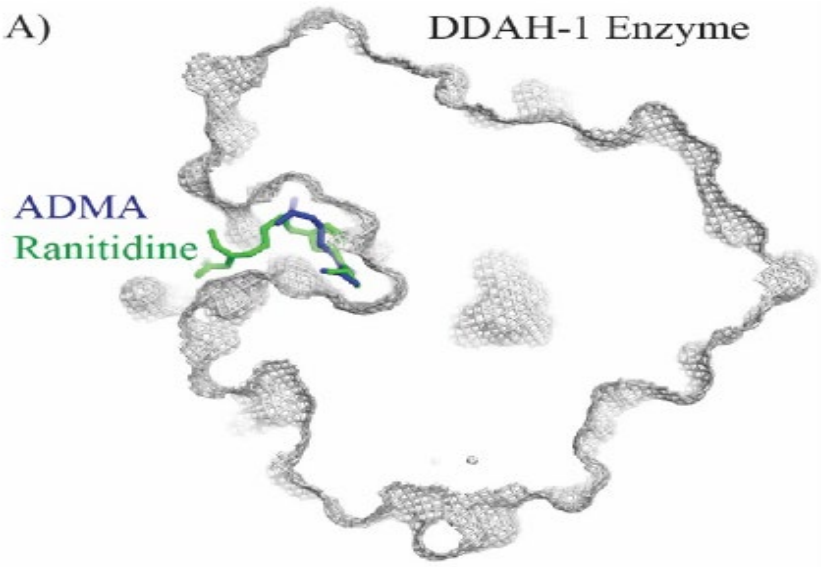
135. In addition to the gastric fluid mechanisms investigated in the scientific literature, Valisure identified a possible enzymatic mechanism for the liberation of ranitidine's DMA group via the human enzyme dimethylarginine dimethylaminohydrolase ("DDAH"), which can occur in other tissues and organs separate from the stomach.

136. Valisure explained that liberated DMA can lead to the formation of NDMA when exposed to nitrite present on the ranitidine molecule, nitrite freely circulating in the body, or other potential pathways, particularly in weak acidic conditions such as that in the kidney or bladder. The original scientific paper detailing the discovery of the DDAH enzyme in 1989 specifically comments on the propensity of DMA to form NDMA: "This report also provides a useful knowledge for an understanding of the endogenous source of dimethylamine as a precursor of a potent carcinogen, dimethylnitrosamine [NDMA]."[44]

[44] Ogawa, *et al*., *supra* note 28.

137. Valisure reported as illustrated in Figure 2, below, computational modelling demonstrates that ranitidine (shown in green) can readily bind to the DDAH-1 enzyme (shown as a cross-section in grey) in a manner similar to the natural substrate of DDAH-1 known as asymmetric dimethylarginine ("ADMA," shown in blue).

Figure 2 – Computational Modelling of Ranitidine Binding to DDAH-1 Enzyme



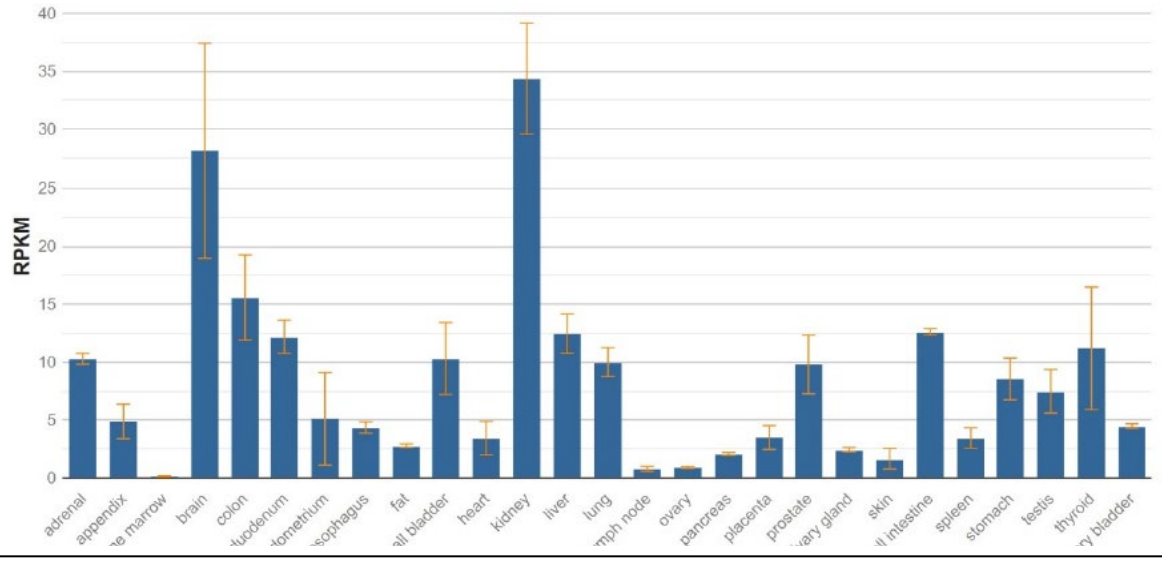
B)

	Predicted Affinity (kcal/mol)
ADMA	-5.9 ± 0.2
[illegible]	[illegible]

138. Valisure reported that these results suggest that the enzyme DDAH-1 increases formation of NDMA in the human body when ranitidine is present; therefore, the expression of the DDAH-1 gene is useful for identifying organs most susceptible to this action.

139. Figure 3 below, derived from the National Center for Biotechnology Information, illustrates the expression of the DDAH-1 gene in various tissues in the human body.

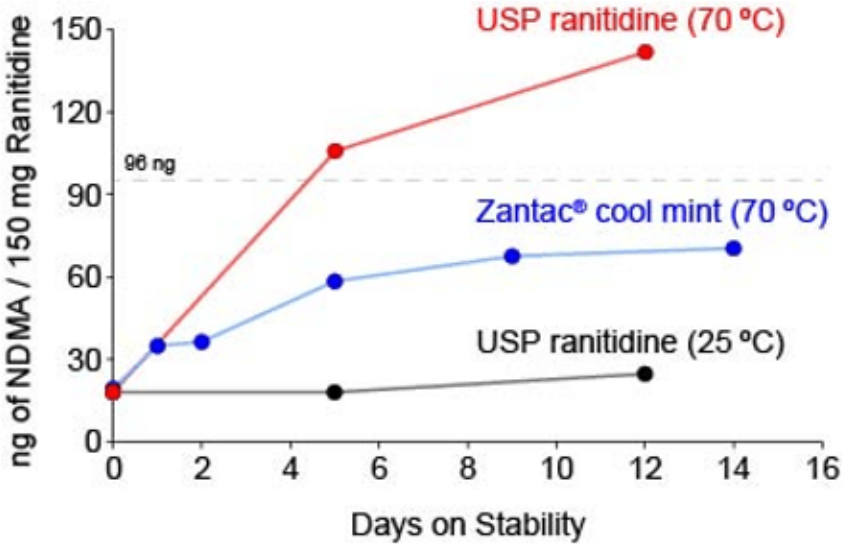
Figure 3 – Expression levels of DDAH-1 enzyme by Organ



140. DDAH-1 is most strongly expressed in the kidneys but also broadly distributed throughout the body, such as in the brain, colon, liver, small intestine, stomach, bladder, and prostate. Valisure noted that this offers both a general mechanism for NDMA formation in the human body from ranitidine and specifically raises concern for the effects of NDMA on numerous organs.

141. The possible enzymatic reaction of ranitidine to DDAH-1, or other enzymes, suggests that high levels of NDMA can form throughout the human body. Indeed, ranitidine metabolizes and circulates throughout the human body, crossing the placental and blood-brain barrier, within 1-2 hours. When ranitidine interacts with the DDAH-1 enzyme in various organs throughout the body, it breaks down into NDMA. This observation is validated by the Stanford study, discussed above.

Figure 4 – Rate of Development of NDMA when Exposed to Heat



C. Formation of NDMA by Exposure to Heat, Moisture, and/or Time

142. The risk of creating NDMA by exposing ranitidine to heat has been well-known and documented. Early studies, including the one conducted by GSK in the early 1980s, demonstrated that nitrosamines were formed when ranitidine was exposed to heat. This point was underscored in the Valisure petition, which initially used a high-heat testing method.

143. In response to Valisure, the FDA recommended that researchers use the LC-HRMS protocol for detecting NDMA in ranitidine because the "testing method does not use elevated temperatures" and has been proven capable of detecting NDMA. Emery Pharma, an FDA-certified pharmaceutical testing laboratory, conducted a series of tests on ranitidine. The researchers exposed ranitidine to 70 ˚C for varying periods of time. The results showed that increasing levels of NDMA formed based on exposure to heat. As reported by Emery Pharma, the following diagram reveals how NDMA accumulates over time when exposed to 70 ˚C:

144. The researchers cautioned:

> NDMA accumulates in ranitidine-containing drug products on exposure to elevated temperatures, which would be routinely reached during shipment and during storage. More importantly, these conditions occur post-lot release by the manufacturer. Hence, while NDMA levels in ranitidine may be acceptable at the source, they may not be so when the drug is purchased and subsequently at the time of consumption by the consumer.[45]

145. The results of this data demonstrate that in normal transport and storage, and especially when exposed to heat or humidity, the ranitidine molecule systematically breaks down into NDMA, accumulating over time in the finished product. Considering ranitidine-containing products have an approved shelf life of 36 months, the possibility of the drug accumulating dangerously high levels of NDMA prior to consumption is very real—a point underscored by the FDA's swift removal of the product from the market.

146. In fact, the FDA acknowledged that testing revealed that NDMA levels in ranitidine products stored at room temperature can increase with time to unacceptable levels.

147. The findings by Valisure unleashed an avalanche of regulatory authorities throughout the world demanding that the manufacturers of Zantac and/or ranitidine conduct testing of their products for the presence of NDMA as well as investigate the root cause as to how NDMA was being generated. In April 2020, the FDA requested that manufacturers immediately remove all ranitidine-containing products from the market.

148. In the interim between the Valisure findings being released to the public and the FDA announcement requesting recall of all ranitidine products in April 2020, the manufacturers were investigating the root cause of NDMA in their products.

149. After undertaking an investigation, GSK concluded that "the presence of NDMA

[45] Emery Pharma, *Emery Pharma Ranitidine: FDA Citizen Petition* (Jan. 2, 2020), *available at* https://emerypharma.com/news/emery-pharma-ranitidine-fda-citizen-petition/.

in ranitidine drug substance is due to a slow degradation reaction occurring primarily in the solid state. The two constituent parts of NDMA, the nitroso group and the dimethylamino group, are both derived from internal degradation reactions which occur at slow rates with the ranitidine molecule."

150. Both brand-name and generic manufacturers could dictate the conditions under which API was transported to them. The labeling requirements do not apply to transporting API, in part because the finished product and API are packaged differently and may degrade under different conditions.

151. Brand-name and generic manufacturers failed to ensure that their Ranitidine-Containing Products (in both API and finished dose form) were kept safely from excessive heat and humidity.

V. EVIDENCE DIRECTLY LINKS RANITIDINE EXPOSURE TO PLAINTIFF'S CANCER

152. In addition to numerous epidemiology studies examining how NDMA causes cancer in humans, researchers have also specifically looked at ranitidine and found an association with bladder, esophageal, and kidney cancer.

153. In one epidemiological study looking at various cancer risks and histamine H_2-receptor antagonists (or H_2 blockers), including ranitidine, the data showed that ranitidine consumption increased the risk of prostate, lung, esophageal, pancreatic, and kidney cancer.[46]

154. A number of studies have been published over the years showing an increased risk of various cancers associated with use of ranitidine and/or H_2 blockers.[47] Research reports have

[46] Laurel A Habel et al., *Cimetidine Use and Risk of Breast, Prostate, and Other Cancers*, 9 Pharmacoepidemiology & Drug Safety 149–55 (2000).

[47] Robert W. Mathes et al., *Relationship Between Histamine2-receptor Antagonist Medications and Risk of Invasive Breast Cancer*, 17 Cancer Epi. Biomarkers & Prevention 1, 67–72 (2008); *see also* Jeong Soo Ahn et al., *Acid*

shown that ranitidine use was associated with a significant increase in the risk of bladder, breast, colorectal/intestinal, esophageal, gastric, kidney, liver, lung, pancreatic, and prostate cancer.[48]

VI. GSK KNEW OR SHOULD HAVE KNOWN OF THE NDMA RISK BEFORE RANTITDINE WAS APPROVED

155. As early as 1981, ***two years before GSK received approval*** for NDA 18-703 and Zantac entered the market, research showed elevated rates of NDMA, when properly tested.[49] This was known or should have been known by all Defendants as the information was available in medical literature.

156. In 1981, GSK, the originator of the ranitidine molecule, published a study focusing on the metabolites of ranitidine in urine using liquid chromatography.[50] Many metabolites were listed, though there is no indication that the study looked for NDMA.

157. Indeed, in that same year, Dr. de Flora published a note discussing the results of his experiments showing that ranitidine was turning into mutagenic N-nitroso compounds, of which NDMA is one, in human gastric fluid when accompanied by nitrites—a substance commonly found in food and in the body.[51] GSK was aware of this study because GSK specifically responded to the note and attempted to discredit it. GSK knew or should have known about this scientific exchange as it was published in a popular scientific journal. GSK was obligated to investigate this issue properly, but it failed to do so.

Suppressive Drugs and Gastric Cancer: A Meta-analysis of Observational Studies, 19 World J. Gastroenterology 16, 2560 (2013); Shih-Wei Lai et al., *Use of Proton Pump Inhibitors Correlates with Increased Risk of Pancreatic Cancer: A Case-control Study in Taiwan*, 46 Kuwait Med J. 1, 44–48 (2014); Poulsen et al., *Proton Pump Inhibitors and Risk of Gastric Cancer – A Population Based Cohort Study*, 100 Brit. J. Cancer 1503–07 (2009); E Wennerström, *Acid-suppressing Therapies and Subsite-specific Risk of Stomach Cancer*, 116 Brit. J. Cancer 9, 1234–38 (2017).

[48] Richard H. Adamson & Bruce A. Chabne, *The Finding of N-Nitrosodimethylamine in Common Medicines,* The Oncologist, June 2020; 25(6): 460–62, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7288647/.

[49] *See supra* ¶ 114 (discussing de Flora research).

[50] Carey et al., *Determination of Ranitidine and Its Metabolites in Human Urine by Reversed-phase Ion-pair High-performance Liquid Chromatography*, 255 J. Chromatography B: Biomedical Sci. & Appl. 1, 161–68 (1981).

[51] De Flora, *supra* note 25.

158. In its original pre-approval submission to the FDA, GSK explained that the level of nitrite present in Zantac would be unrealistic and, thus, these results had no "practical clinical significance." Specifically, GSK stated:

> Although N-nistroso-nitrolic acid was a potent mutagen, it is not likely to be formed in the stomach of a patient ingesting ranitidine, as un unrealistically large amount of nitrite needs to be present to form and maintain the nitrosamine. For this reason, and also because ranitidine was not carcinogenic in life-span studies in rodents, the in vitro nitrosation of ranitidine to a mutagenic nitrosamine does not seem to have practical clinical significance.

159. Around this same time—***before Zantac was approved by the FDA***— GSK conducted another study to examine, among other things, how long-term use of ranitidine could affect the levels of nitrite in the human stomach. Remarkably, in the study that was presented to the FDA, GSK admitted that ranitidine use caused the proliferation of bacteria in the human stomach that are known to convert nitrates to nitrites, which leads to elevated levels of nitrite in the stomach environment. GSK acknowledged this could increase the risk of developing NDMA and, in turn, cancer, but it then dismissed this risk because individuals were allegedly only expected to use ranitidine-containing products for a short-term period. In particular, GSK stated:

> The importance of this finding is not clear. High levels of nitrite could react with certain organic compounds to form nitrosamines, which are known carcinogens. To date, however, neither ranitidine nor cimetidine have been carcinogenic in rodents, so the level of human risk cannot be estimated from animal studies. Ranitidine is recommended only for short-term use and carcinogenic risk, if any, should thus be minimized.

160. GSK knew—and indeed specifically admitted—that ranitidine could react with nitrite in the human stomach to form NDMA and, at the same time, that long-term use of ranitidine could lead to elevated levels of nitrite in the human stomach.

161. In response to Dr. de Flora's findings, in 1982, GSK conducted a clinical study

specifically investigating gastric contents in human patients. The study, in part, specifically measured the levels of N-Nitroso compounds in human gastric fluid. GSK indicated that there were no elevated levels, and even published the results of this study five years later, in 1987. That study, however, was also rigged. GSK did not use gold-standard mass spectrometry to test for NDMA; it instead used a process that could not measure N-nitrosamines efficiently. And worse, in the testing it did do, GSK refused to test gastric samples that contained ranitidine in them out of concern that samples with ranitidine would contain "high concentrations of N-nitroso compounds being recorded." In other words, GSK intentionally rigged the study to exclude the very samples most likely to contain a dangerous carcinogen.

162. By 1987, after numerous studies raised concerns over ranitidine and cancerous nitroso compounds, GSK published a clinical study specifically investigating gastric contents in human patients and N-nitroso compounds.[52] That study specifically indicated that there were no elevated levels of N-nitroso compounds (of which NDMA is one). But the study was flawed. It used an analytical system called a "nitrogen oxide assay" for the determination of N-nitrosamines, which was developed for analyzing food and is a detection method that indirectly and non-specifically measures N-nitrosamines. Not only is that approach not accurate, but GSK also removed all gastric samples that contained ranitidine out of concern that samples with ranitidine would contain "high concentrations of N-nitroso compounds being recorded." Without the chemical being present in any sample, any degradation into NDMA could not, by design, be observed. The inadequacy of that test was knowable in light of its scientific publication in 1987. All Defendants either knew or should have known about the inadequacy of that study and should have investigated the issue properly and/or took action to protect consumers from the NDMA risks

[52] Thomas et al., *supra* note 39.

in their products. None did.

163. In a 1995 epidemiological case-control study looking at NDMA dietary exposure with 220 cases, researchers observed a statistically significant 700% increased risk of gastric cancer in persons exposed to more than 0.51 ng of NDMA per day. In a 1995 epidemiological case-control study looking at NDMA dietary exposure with 746 cases, researchers observed statistically significant elevated rates of gastric cancer in persons exposed to more than 0.191 ng of NDMA per day. In another 1995 epidemiological case-control study looking at, in part, the effects of dietary consumption on cancer, researchers observed a statistically significant elevated risk of developing aerodigestive cancer in individuals who were exposed to 0.179 ng of NDMA per day.

164. In a 1999 epidemiological cohort study looking at NDMA dietary exposure with 189 cases and a follow up of 24 years, researchers noted that "N-nitroso compounds are potent carcinogens" and that dietary exposure to NDMA more than doubled the risk of developing colorectal cancer.

165. In a 2000 epidemiological cohort study looking at occupational exposure of workers in the rubber industry, researchers observed significant increased risks for NDMA exposure for esophagus, oral cavity, pharynx, prostate, and brain cancer.

166. In a 2011 epidemiological cohort study looking at NDMA dietary exposure with 3,268 cases and a follow-up of 11.4 years, researchers concluded that "[d]ietary NDMA intake was significantly associated with increased cancer risk in men and women" for all cancers, and that "NDMA was associated with increased risk of gastrointestinal cancers" including rectal cancers.

167. In a 2014 epidemiological case-control study looking at NDMA dietary exposure

with 2,481 cases, researchers found a statistically significant elevated association between NDMA exposure and colorectal cancer.

168. In addition to studies demonstrating that NDMA directly causes cancer, research shows that exposure to NDMA (1) can exacerbate existing but dormant (i.e. not malignant) cancers, (2) promote otherwise "initiated cancer cells" to develop into cancerous tumors; and (3) reduce the ability of the body to combat cancer. Thus, in addition to NDMA being a direct cause of cancer itself, NDMA can also be a contributing factor to a cancer injury caused by some other source.

169. NDMA is also known to be genotoxic, which means it can cause DNA damage in human cells. Indeed, multiple studies demonstrate that NDMA is genotoxic both in vivo and in vitro. However, recent studies have shown that the ability of NDMA to cause mutations in cells is affected by the presence of enzymes typically found in living humans, suggesting that "humans may be especially sensitive to the carcinogenicity of NDMA."

VII. THE FEDERAL REGULATORY LANDSCAPE

170. A manufacturer is required to give adequate directions for the use of a pharmaceutical drug such that a "layman can use a drug safely and for the purposes for which it is intended,"[53] and conform to requirements governing the appearance of the label.[54]

171. "Labeling" encompasses all written, printed or graphic material accompanying the drug or device,[55] and therefore broadly encompasses nearly every form of promotional activity, including not only "package inserts" but also advertising.

172. "Most, if not all, labeling is advertising. The term 'labeling' is defined in the FDCA

[53] 21 C.F.R. § 201.5.
[54] *Id.* § 201.15.
[55] *Id.*; 65 Fed. Reg. 14286 (Mar. 16, 2000).

as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising."[56]

173. All drug manufacturers (brand and generic) are also responsible for conducting stability testing, which must be "designed to assess the stability characteristics of drug products."[57] Manufacturers must adopt a written testing program that includes: "(1) Sample size and test intervals based on statistical criteria for each attribute examined to assure valid estimates of stability; (2) Storage conditions for samples retained for testing; (3) Reliable, meaningful, and specific test methods; (4) Testing of the drug product in the same container-closure system as that in which the drug product is marketed; (5) Testing of drug products for reconstitution at the time of dispensing (as directed in the labeling) as well as after they are reconstituted."[58]

174. The purpose of stability testing is, in part, to determine the "appropriate storage conditions and expiration dates."[59] And expiration dates, in turn, must be set to "assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use."[60] An expiration date is "related to any storage conditions stated on the labeling, as determined by stability studies listed in § 211.166."[61]

175. Each manufacturer, whether brand or generic, must conduct its own tests to determine and set accurate retest or expiration dates.

176. The FDA made clear when it first adopted the expiration-date provision that the regulation means what it says. The purpose of the expiration date is not merely to consider the "stability of a specific active ingredient." Instead, a compliant expiration date must account for

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[56] *United States v. Research Labs.*, 126 F.2d 42, 45 (9th Cir. 1942).
[57] 21 C.F.R. § 211.166(a).
[58] *Id.*
[59] *Id.*
[60] *Id.* § 211.137(a).
[61] *Id.* § 211.137(b).

multiple factors, including "the stability of the inactive ingredients, the interaction of active and inactive ingredients, the manufacturing process, the dosage form, the container closure system, the conditions under which the drug product is shipped, stored, and handled by wholesalers and retailers, and the length of time between initial manufacture and final use."[62]

177. The FDA expressly recognizes that an initial expiration date may not be the final expiration date: "Where data from accelerated studies are used to project a tentative expiration date that is beyond a date supported by actual shelf-life studies, there must be stability studies conducted . . . until the tentative expiration date is verified or the appropriate expiration date determined."[63]

178. After a drug is approved, a manufacturer can make changes to its drug application. To do so, manufacturers must comply with the requirements of §§ 314.70 and 314.71.

179. Some of the requirements in those regulations require a manufacturer of an approved drug to obtain FDA approval before implementing a label change.[64]

180. But the FDA has long recognized a "changes being effected" ("CBE") supplement that permits a manufacturer to make immediate changes, subject to FDA's post-change review.[65]

181. A manufacturer of an approved drug can use the CBE supplement to immediately make an "[a]ddition to a specification or changes in the methods or controls to provide increased assurance that the drug substance or drug product will have the characteristics of identity, strength quality, purity, or potency that it purports or is represented to possess."[66] "A specification is defined as a list of tests, references to analytical procedures, and appropriate acceptance criteria

[62] 43 Fed. Reg. 45059 (Sept. 29, 1978).
[63] 21 C.F.R. § 211.166(b).
[64] *Id.* § 314.70(b).
[65] *Id.* § 314.70(c)(3), (c)(6).
[66] *Id.* § 314.70(c)(6)(i).

that are numerical limits, ranges, or other criteria for the tests described."[67]

182. A manufacturer, therefore, need not seek FDA pre-approval to make changes to its stability studies to identify the appropriate expiration date—which must "assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use"[68]—or to ensure that the drug is shipped and stored under appropriate conditions.

183. A manufacturer of an approved drug can also use the CBE supplement to make "moderate" changes "in the labeling to reflect newly acquired information" in order to "add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the labeling under § 201.57(c) of this chapter"; "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product"; and "delete false, misleading, or unsupported indications for use or claims for effectiveness."[69]

184. Thus, GSK, Pfizer, and Boehringer Ingelheim could have made these changes to their several NDAs for Zantac. Any change GSK made to its prescription Zantac labels to strengthen warnings when it first held the under NDAs 18-703, 20-095, and 20-251 NDAs 20-520 and 20-745 would have warned Plaintiff about the presence of NDMA and the increased risk of cancer.

185. Furthermore, any change GSK made to its OTC Zantac labels to strengthen warnings when it first held NDAs 20-520 and 20-745 would have been passed to Pfizer and Boehringer Ingelheim when they took over the NDAs. Similarly, any change Pfizer made to its Zantac label to strengthen warnings when it first held the NDAs 20-520, 20-745, and 21-698 would

[67] 65 Fed. Reg. 83042 (Dec. 29, 2000).
[68] 21 C.F.R. § 211.137(a).
[69] *Id.* § 314.70(c)(6)(iii)(A), (C), (D).

have been passed to Boehringer Ingelheim when they took over the NDAs.

186. Also, at no time did the Brand Defendants, in concert or individually, seek to make a change to the labels and warnings of Zantac to warn about the risk of cancer associated with NDMA. However, they did seek to make CBE regulation changes to all of these NDAs for other commercial purposes, which were approved by the FDA.

187. Also, a manufacturer of an approved drug may make minor changes to a label with no approval or notice, so long as that change is described in an annual report. The illustrative but non-exhaustive list of minor changes includes "[a] change in the labeling concerning the description of the drug product or in the information about how the drug product is supplied, that does not involve a change in the dosage strength or dosage form."[70]

188. A "minor change" further includes "[a]n extension of an expiration dating period based upon full shelf-life data on production batches obtained from a protocol approved in the NDA."[71]

189. At no time did any of the Brand Defendants attempt to include a warning on the labels for ranitidine-containing products such as Zantac that consumers were at elevated risk of developing cancer if the products were: (i) exposed to excessive heat; (ii) exposed to excessive moisture/humidity; (iii) consumed with high-nitrite foods; (iv) consumed daily for a period of greater than a few months. The FDA never rejected such cancer warnings.

190. At no time did any of the Brand Defendants attempt to change their labels on Zantac to delete a false or misleading expiration date, or to add a proper expiration date to ensure that ranitidine-containing products would not break down into NDMA prior to human consumption.

191. Based on the public scientific information, the Brand Defendants knew or should

[70] *Id.* § 314.70 (d)(2)(ix).
[71] *Id.* § 314.70 (d)(2)(vi); *see also id.* § 314.70(d)(2)(vii), (x).

have known that NDMA could form in ranitidine and Zantac by exposure to heat, humidity, nitrites, the conditions of the human stomach, and/or over time in storage.

192. At no time did any of the Brand Defendants change their labels on Zantac to shorten the expiration date. The Brand Defendants had the ability to unilaterally make such label changes for Zantac without prior FDA approval pursuant to the CBE regulation. Had any of the Brand Defendants attempted such label changes, the FDA would not have rejected them.

193. Because they failed to include appropriate expiration dates on their Zantac products, the Brand Defendants made false statements in the labeling of their Zantac products.

VIII. FEDERAL LAW REQUIRED THE BRAND DEFENDANTS TO NOTIFY THE FDA ABOUT THE PRESENCE OF NDMA IN RANITIDINE-CONTAINING PRODUCTS SUCH AS ZANTAC

194. During the time that the Brand Defendants manufactured and sold ranitidine-containing products such as Zantac in the United States, the weight of scientific evidence showed that ranitidine exposed users to unsafe levels of NDMA. The Brand Defendants failed to report these risks to the FDA.

195. The Brand Defendants concealed the ranitidine-NDMA link from ordinary consumers in part by not reporting it to the FDA, which relies on drug manufacturers (or others, such as those who submit citizen petitions) to bring new information about an approved drug like ranitidine to the agency's attention.

196. Manufacturers (brand and generic) of an approved drug are required by regulation to submit an annual report to the FDA containing, among other things, new information regarding the drug's safety pursuant to 21 C.F.R. § 314.81(b)(2):

> The report is required to contain . . . [a] brief summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product. The report is also required to contain a brief description of actions the applicant has taken or intends to

> take as a result of this new information, for example, submit a labeling supplement, add a warning to the labeling, or initiate a new study.

197. 21 C.F.R. § 314.81(b)(2)(v) provides that the manufacturer's annual report must also contain:

> Copies of unpublished reports and summaries of published reports of new toxicological findings in animal studies and in vitro studies (*e.g.*, mutagenicity) conducted by, or otherwise obtained by, the [manufacturer] concerning the ingredients in the drug product.

198. Every approval letter for an NDA issued to GSK or Pfizer, and transferred to the other Brand Defendants, contained the following directive from the FDA:

> **We remind you that you must comply with the requirements for an approved NDA set forth under 21 C.F.R. 314.80 and 314.81.**

199. The Brand Defendants ignored these regulations and, disregarding the scientific evidence available to them regarding the presence of NDMA in their Zantac products and the risks associated with NDMA, did not report to the FDA significant new information affecting the safety or labeling of ranitidine-containing products such as Zantac.

200. The Brand Defendants ignored these regulations and, disregarding the scientific evidence available to them regarding the presence of NDMA in their products and the risks associated with NDMA, did not report to the FDA significant new information affecting the safety or labeling of ranitidine-containing products such as Zantac.

201. Knowledge regarding the risk of NDMA in ranitidine was sufficiently available in the publicly available scientific literature such that any manufacturer, consistent with its heightened obligations to ensure the safety of its products, also should have known about the potential NDMA risks associated with ranitidine consumption.

202. The Brand Defendants never conducted or provided the relevant studies to the FDA, nor did they present the FDA with a proposed disclosure noting the various ways that ranitidine

transforms into NDMA. Accordingly, because the Brand Defendants never properly disclosed the risks to the FDA, they never proposed any labeling or storage/transportation guidelines that would have addressed this risk. Thus, the FDA was never able to reject any proposed warning or proposal for transport/storage.

203. When the FDA eventually learned about the NDMA risks posed by ranitidine-containing products, it ordered manufacturers to voluntarily remove the products from the market. Thus, had any of the Brand Defendants alerted the FDA to the risks of NDMA, the FDA would have required the manufacturers to remove ranitidine-containing products such as Zantac from the market.

IX. GOOD MANUFACTURING PRACTICES

204. Under federal law, a manufacturer must manufacture, store, warehouse, and distribute pharmaceutical drugs in accordance with "Current Good Manufacturing Practices" ("CGMPs") to ensure they meet safety, quality, purity, identity, and strength standards.[72]

205. 21 C.F.R. § 210.1(a) states that the CGMPs establish "minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess." Entities at all phases of the design, manufacture, and distribution chain are bound by these requirements.

206. Pursuant to 21 C.F.R. § 211.142(b), the warehousing of drug products shall provide for "[s]torage of drug products under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity of the drug products are not affected." In other

[72] 21 U.S.C. § 351(a)(2)(B).

words, all Defendants had a duty and were obligated to properly store, handle, and warehouse ranitidine and ranitidine-containing products such as Zantac.

207. Testing conducted by the FDA confirms that under accelerated conditions the elevated temperatures can lead to the presence of NDMA in the drug product.[73] FDA has also concluded that NDMA can increase in ranitidine under storage conditions allowed by the labels, and NDMA has been found to increase significantly in samples stored at higher temperatures, including temperatures the product may be exposed to during normal distribution and handling. FDA's testing also showed that the level of NDMA in ranitidine-containing products increases with time. And while Emery's Citizen Petition sought to obtain a directive regarding temperature-controlled shipping of ranitidine, which was necessary given the time and temperature sensitivity of the drug, that request was deemed moot by the FDA because the agency sought to withdraw ranitidine-containing products altogether.

208. Nothing prevented any Defendant from, on their own, taking actions to prevent accumulation of NDMA in ranitidine-containing products by ensuring that ranitidine was not exposed to heat or moisture over long periods.

X. WALGREENS ALLEGATIONS

209. Walgreens states that it understands that "consumers want to feel confident the products they use are safe for their intended purposes."[74]

210. Walgreens claims it aims to do "business fairly and with integrity" which has led Walgreens to "drive responsible sourcing practices throughout our supply chain, protecting human rights and engaging with suppliers around ethical and environmental issues."[75]

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[73] Woodcock Letter, *supra* note 38.

[74] https://www.walgreens.com/topic/sr/sr_product_integrity_home.jsp (last accessed Nov. 23, 2021).

[75] https://www.walgreensbootsalliance.com/sites/www/files/asset/Walgreens-Boots-Alliance-2019-Corporate-Social-Responsibility-Report_2.pdf (last accessed Nov. 20, 2021).

211. According to Walgreens, "[p]atient safety lies at the heart of our management of pharmacy operations, and we strive to be the industry leader by continuously seeking ways to minimize risks to patients in our dispensing, pharmacy services and advance and pharmacy supply chain operations."[76]

212. Walgreens claims it engages in "ongoing supplier ethical compliance assessments" which includes "engaging with suppliers to improve when issues are detected."

213. Walgreens also claims to screen suppliers against a matrix which assesses the suppliers' management systems to discern whether they are operating in any way which violates Walgreens' ethical sourcing commitments.[77]

214. Walgreens' supplier requirements demonstrate its knowledge that it is ultimately responsible for ensuring that (a) all of its products comply with CGMPs, (b) are not adulterated for failure to comply with CGMPs, and (c) are not misbranded.

215. Pursuant to 21 C.F.R. §211.142(b), the warehousing of drug products shall provide for "[s]torage of drug products under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity of the drug products are not affected." Walgreens thus had a duty and was obligated to properly store, handle, and warehouse Zantac.

216. Testing conducted by the FDA confirms that improper storage of ranitidine has resulted in extremely high levels of NDMA. The FDA has also concluded that NDMA can increase in ranitidine even under storage conditions allowed by the labels, and NDMA has been found to increase significantly in samples stored at higher temperatures, including temperatures the product may be exposed to during normal distribution and handling. FDA's testing also showed that the level of NDMA in ranitidine-containing products increases with time. And while Emery's Citizen

[76] *Id.*
[77] *Id.*

Petition sought to obtain a directive regarding temperature-controlled shipping of ranitidine, which was necessary given the time and temperature sensitivity of the drug, that request was deemed moot by the FDA because the agency sought to withdraw ranitidine-containing products altogether.

217. Nothing prevented Walgreens from, on its own, taking actions to prevent accumulation of NDMA in Zantac products by ensuring storage and transport at the lower end of the temperature range contained on the labels. Nothing prevented Walgreens from ensuring that Zantac was not exposed to humidity or moisture.

218. In fact, Walgreens says that its "products . . . are rigorously analyzed for compliance with all applicable laws and regulations" as well as Walgreens' "*own higher standards*," and that its "own product safety analysis" sometimes "come to a *different, stricter* conclusion than some regulatory bodies." (Emphasis added).[78]

219. Based on the public scientific information, Walgreens knew or should have known that NDMA could form in ranitidine by exposure to heat, humidity, nitrites, the conditions of the human stomach, and/or over time in storage.

220. Based on the public scientific information, Walgreens had a duty to monitor for and/or discover defects in Zantac products.

221. Walgreens knew or should have known that Zantac had an inherent risk of degrading into NDMA because it has both a nitroso (N) and dimethylamine (DMA), which are all the ingredients needed to form NDMA.

222. The Zantac products the Plaintiff consumed had excessive levels of NDMA in part because they were subjected to high levels of humidity and were stored for a long period of time

[78] https://www.walgreens.com/topic/sr/sr_product_integrity_home.jsp (last accessed Nov. 23, 2021).

(often in humid locations such as bathrooms).

223. During the time that Walgreens distributed and sold Zantac products in the United States, the weight of scientific evidence showed that ranitidine exposed users to unsafe levels of NDMA.

224. Walgreens failed to disclose that risk to consumers on the drug's label—or through any other means—and they failed to report those risks to the FDA.

225. The U.S. Pharmacopeia Convention (hereinafter "USP") sets forth industry standards applicable—in relevant part—to distributors. Chapter 1079, entitled "Good Storage and Shipping Practices," specified at relevant times:

> Good storage and distribution practices apply to all organizations and individuals involved in any aspect of the storage and distribution of all drug products, including but not limited to the following: . . .Wholesale distributors; distribution companies involved in automobile, rail, sea, and air services.

226. USP 1079 states: "[A]ll organizations along the supply chain bear responsibility for ensuring that they handle drug products within adequate storage and distribution parameters that will not affect the drug product identity, strength, quality, purity, or safety."

227. As previously stated, research laboratory Emery Pharma submitted a Citizens Petition to the FDA showing that NDMA accumulates in ranitidine at unsafe rates when exposed to label-compliant temperature ranges that would occur during normal transport and storage conditions.

228. Emery's Citizen Petition outlined its substantial concern that ranitidine is a time and temperature-sensitive pharmaceutical product that develops NDMA when exposed to heat, a common occurrence during shipping, handling, and storage. In addition to warning about this condition, Emery requested agency directives to manufacturers and distributors to ship ranitidine in temperature-controlled vehicles.

229. The FDA found its stability testing raised concerns that NDMA levels in some ranitidine-containing products stored at room temperature can increase with time to unacceptable levels. In the same vein, FDA testing revealed NDMA levels were higher as the products approached their expiration dates. The FDA's testing eroded the agency's confidence that any ranitidine-containing product could remain stable through its labeled expiration date.

XI. RANITIDINE-CONTAINING PRODUCTS SUCH AS ZANTAC ARE MISBRANDED AND ADULTERATED BECAUSE THEY CONTAIN DANGEROUS AND BIOLOGICALLY RELEVANT LEVELS OF NDMA

230. The manufacture of any misbranded or adulterated drug is prohibited under federal law.[79]

231. The introduction into commerce of any misbranded or adulterated drug is similarly prohibited.[80]

232. Similarly, the receipt in interstate commerce of any adulterated or misbranded drug is also unlawful.[81]

233. Among the ways a drug may be adulterated and/or misbranded is: "If it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof."[115]

234. As recent regulatory action confirms, ranitidine was dangerous to health when used as prescribed.

235. It is unlawful to introduce a misbranded drug into interstate commerce.[116] Thus, the Zantac ingested by Plaintiff was unlawfully distributed and sold.

236. Plaintiff purchased brand-name Zantac from Walgreens from 1998 until 2010.

[79] 21 U.S.C. § 331(g).
[80] *Id.* § 331(a).
[81] *Id.* § 331(c).
[115] 21 U.S.C. § 352(j).

Plaintiff ingested the brand-name Zantac that she purchased from Walgreens over the course of those years.

237. GSK and Pfizer marketed branded OTC Zantac from 1995 to 1998, which GlaxoSmithKline manufactured. Pfizer then marketed branded OTC Zantac from 1998 to 2006, which GlaxoSmithKline manufactured. Boehringer Ingelheim manufactured and marketed branded OTC Zantac from 2007 to 2016. At all times from 1983 to 2017 GlaxoSmithKline marketed prescription Zantac.

238. Plaintiff, therefore, ingested branded Zantac manufactured or marketed by GSK, Pfizer, and Boehringer Ingelheim.

239. The Zantac Plaintiff consumed used the same defective labels devised by GSK originally and subsequently adopted by Pfizer, and Boehringer Ingelheim.

240. The amount of Zantac Plaintiff ingested that is attributable to each Brand Defendant was more than de minimis; each Brand Defendants' actions were a substantial contributing factor to Plaintiff's cancer and subsequent injuries.

DEFENDANTS' WARRANTIES AND REPRESENTATIONS

I. GSK'S WARRANTIES AND REPRESENTATIONS

241. GSK's ranitidine-containing Zantac product is accompanied by an FDA-approved label. By presenting consumers with an FDA-approved label, GSK made representations and express or implied warranties to consumers like Plaintiff that its products were consistent with the safety, quality, purity, identity, and strength characteristics reflected in the FDA-approved labels and/or were not adulterated and/or misbranded.

242. In addition, GSK affirmatively misrepresented and warranted to physicians and patients like Plaintiff through their websites, brochures, and other marketing or informational

materials that their ranitidine-containing products complied with CGMPs and did not contain (or were not likely to contain) any ingredients besides those identified on the products' FDA-approved labels.

243. The presence of NDMA in GSK's ranitidine-containing products resulted in GSK's ranitidine-containing products containing an ingredient that is not also listed on GSK's FDA-approved label. GSK willfully, recklessly, or negligently failed to ensure that its ranitidine-containing products' labels and other advertising or marketing statements accurately conveyed information about its ranitidine-containing products.

244. Due to its status as a probable human carcinogen as listed by both the IARC and the EPA, NDMA is not an FDA-approved ingredient. Thus, GSK's ranitidine-containing products are adulterated and/or misbranded, and it was illegal for GSK to have introduced such ranitidine into commerce in the United States.[117]

II. WALGREENS' WARRANTIES AND REPRESENTATIONS

245. By selling drugs in the stream of commerce, Walgreens warranted to consumers such as Plaintiff that the ranitidine-containing products it sold were safe and effective.

246. During this relevant time period, Plaintiff purchased OTC Zantac from Walgreens pharmacies, which, provided Plaintiff with brand-name Zantac.

247. During these relevant time periods, Plaintiff regularly ingested the Zantac obtained from Walgreens pharmacies.

248. Plaintiff never would have purchased Zantac from any Walgreens pharmacies and Plaintiff never would have ingested any of the Zantac obtained from Walgreens pharmacies if the label and labeling for Zantac during the relevant times listed herein contained warnings and/or

[117] *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B), 331(g).

discussed the risks of developing cancer from ingesting Zantac.

249. During the time that Plaintiff ingested the Zantac obtained from Walgreens pharmacies, Brand Defendants held the NDAs for several versions of Zantac.

250. As the holders of the NDAs for Zantac, Brand Defendants were responsible for the contents of the warnings and precautions contained in the label and labeling for OTC Zantac, including the failure to include any warnings about the presence of NDMA in Zantac and the risk of developing cancer in individuals who ingested OTC Zantac.

251. As the holders of the NDAs for Zantac, Brand Defendants had the ability to unilaterally add a warning or precaution in the label and labeling for OTC brand-name Zantac to warn prescribing physicians and their patients and consumers such as Plaintiff about newly acquired information as described above related to the presence of NDMA in Zantac and the risks of patients and consumers such as Plaintiff of developing cancer, as a result of ingesting Zantac under the Changes Being Effected process under federal law, which Brand Defendants could have independently initiated without a requirement of prior FDA approval. Accordingly, Brand Defendants had the ability to simultaneously satisfy and comply with its obligations towards Plaintiff and consumers and patients like Plaintiff both under state and federal law.

252. GSK knew or should have known about the new studies and research described above related to the presence of NDMA in Zantac and the risk of developing cancer in individuals who ingest Zantac (i.e., the newly acquired information) before Plaintiff relied on the absence of any warnings in Zantac's label and labeling about NDMA in Zantac or the risk of developing cancer in individuals ingesting Zantac that led to Plaintiff's decision to obtain and ingest Zantac.

253. Based on prevailing scientific evidence, exposure to ranitidine products (and the attendant NDMA) can cause cancer in humans.

254. Plaintiff's cancer was caused by Plaintiff's ingestion of Zantac distributed and sold by Walgreens.

255. Had Brand Defendants warned Plaintiff that ingesting Zantac could lead to exposure to NDMA or, in turn, cancer, Plaintiff never would have ingested Zantac.

TOLLING OF STATUTE OF LIMITATIONS / ESTOPPEL / FRAUDULENT CONCEALMENT

256. Plaintiff asserts all applicable statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including estoppel, equitable tolling, delayed discovery, discovery rule and/or fraudulent concealment.

257. Defendants are estopped from relying on any statute of limitations because of their concealment of the truth regarding the safety of Zantac. Defendants had a duty to disclose the true character, quality, and nature of Zantac because this was non-public information over which Defendants continue to have control. Defendants knew that this information was not available to Plaintiff, Plaintiff's medical providers, and/or health facilities, yet Defendants failed to disclose the information to the public, including to Plaintiff.

258. The expiration of any applicable statute of limitations has been equitably tolled by reason of Defendants' misrepresentations and concealment. Through affirmative misrepresentations and omissions, Defendants actively concealed from Plaintiff the true risks associated with use of Zantac. Due to Defendants' acts and omissions, Plaintiff's physicians were unaware of the increased risk of multiple types of cancer associated with the use of ranitidine due to its degradation into NDMA. Plaintiff's physicians did not warn Plaintiff of the true risks of ingesting Zantac including the increased risk of cancer. During the limitations period, Plaintiff could not reasonably have known or learned through reasonable diligence that Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of

Defendants' acts and omissions.

259. Within the time period of any applicable statute of limitations, Plaintiff could not have discovered through the exercise of reasonable diligence that exposure to Zantac is injurious to human health. Plaintiff's physicians did not warn Plaintiff that the true risks of ingesting NDMA in ranitidine included the increased risk of cancer. Plaintiff did not discover and did not know of facts that would cause a reasonable person to suspect the risk associated with the use of Zantac, nor would a reasonable and diligent investigation by Plaintiff have disclosed that Zantac would cause Plaintiff's injuries.

260. Despite acting with reasonable diligence, Plaintiff did not learn of the link between Plaintiff's cancer and Zantac exposure until a time within the statute of limitations for filing of Plaintiff's claims.

COUNT I
STRICT PRODUCTS LIABILITY – PRE-APPROVAL DESIGN DEFECT
(As to GSK and Pfizer)

261. Plaintiff adopts, realleges, and incorporates by reference each allegation set forth in the preceding paragraphs as if fully stated herein.

262. GSK was the inventor of ranitidine and was the developer of prescription Zantac under NDA 18-709, 19-675, 20-095, and 20-251. GSK was also the developer of the various prescription and OTC Zantac products approved under NDAs 20-520 and 20-745, and all supplements. Pfizer was the developer of various OTC Zantac products approved under NDA 21-698 and all supplements.

263. NDAs 18-709, 19-675, 20-095, 20-251, 20-520, 20-745, and 21-698, and their respective supplements, were approved as new NDAs under section 505(b) of the FDCA.

264. GSK and Pfizer, as inventors and developers, knew or, by the exercise of reasonable

care, should have known, ordinary consumers such as Plaintiff would not have realized the potential risks and dangers of Zantac.

265. GSK and Pfizer owed a duty to all reasonably foreseeable users to design a safe product.

266. GSK and Pfizer breached their duty by failing to use reasonable care in the design of Zantac because the drug exposed users to unsafe levels of the carcinogen NDMA.

267. GSK and Pfizer breached their duty by failing to use reasonable care in the design of Zantac by negligently designing the drug with an inherent susceptibility to form NDMA. Alternative designs of the molecule—designs that were approved by the FDA—existed that substantially reduced the degradation of ranitidine into unsafe levels of NDMA.

268. GSK and Pfizer breached their duty by failing to use reasonable care in the design of their respective Zantac products before they were approved by the FDA:

a. When placed in the stream of commerce, Zantac was defective in design and formulation, and, consequently, dangerous to an extent beyond that which an ordinary consumer would contemplate;

b. When placed in the stream of commerce, Zantac was unreasonably dangerous in that it was hazardous and posed a grave risk of cancer and other serious illnesses when used in a reasonably anticipated manner;

c. When placed in the stream of commerce, Zantac contained unreasonably dangerous design defects and were not reasonably safe when used in a reasonably anticipated or intended manner;

d. Prior to approval by the FDA, GSK and Pfizer did not sufficiently test, investigate, or study Zantac and, specifically, the ability for Zantac to transform into the carcinogenic compound NDMA within the human body;

e. Prior to approval by the FDA, GSK and Pfizer did not sufficiently test, investigate, or study Zantac and, specifically, the stability of ranitidine and the ability for ranitidine-containing products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

f. GSK and Pfizer failed to provide accurate expiration dates on the product label prior to the time such label was originally approved by the FDA;

g. Prior to approval by the FDA, GSK and Pfizer failed to propose packaging for their Zantac which would have preserved the safety, efficacy, quality, and purity of the product;

h. Prior to approval by the FDA, GSK and Pfizer failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage of the drug;

i. Prior to approval by the FDA, GSK and Pfizer knew or should have known their exposure to ranitidine could result in cancer and other severe illnesses and injuries;

j. Prior to approval by the FDA, GSK and Pfizer did not conduct adequate stability testing of their product to ascertain shelf life, expiration, and proper storage, heat, and light specifications;

k. Exposure to ranitidine-containing drugs such as Zantac presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug; and

l. Prior to approval by the FDA, GSK and Pfizer possessed a columnar grade I ranitidine drug substance that was chemically identical to the ranitidine used in the products consumed by Plaintiff but was significantly less prone to degrade into NDMA. This morphology of ranitidine was available for use in the United States, but GSK and Pfizer chose to use an inferior design.

269. Prior to approval by the FDA, GSK and Pfizer could have employed safer alternative designs and formulations. For example, GSK and Pfizer could have added ascorbic acid (Vitamin C) to each dose of OTC Zantac, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

270. At the time of submitting the original proposed label for their Zantac products, GSK and Pfizer could have provided warnings or instructions regarding the full and complete risks of ranitidine because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products. Despite this ability, GSK and Pfizer failed to

warn Plaintiff of the risks of NDMA and in the warnings and precautions section of their Zantac products' label.

271. A reasonable company under the same or similar circumstances would have designed a safer product.

272. Had GSK and Pfizer provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Zantac products on the warnings and precautions section of their products' labels, Plaintiff could and would have avoided the risk of developing cancer and could and would have obtained alternative medication.

273. GSK's and Pfizer's defective design of Zantac products was willful, wanton, malicious, and conducted with reckless disregard for the health and safety of users of the Zantac products, including Plaintiff. GSK and Pfizer risked the lives of consumers and users of their products, including Plaintiff, with knowledge of the safety problems associated with ranitidine-containing products, and suppressed this knowledge from the general public. GSK and Pfizer made conscious decisions not to warn or inform the unsuspecting public.

274. The defects in GSK's and Pfizer's Zantac products were substantial and contributing factors in causing Plaintiff's injuries, and, but for GSK's and Pfizer's misconduct and omissions, Plaintiff would not have sustained injuries.

275. As a direct and proximate result of GSK and Pfizer placing their defective Zantac products into the stream of commerce, and the resulting injuries, Plaintiff sustained personal injuries, mental anguish, loss of income, loss of earning capacity, pecuniary loss, and other damages which exceeds the jurisdictional minimum of this Court.

COUNT II
NEGLIGENCE – PRE-APPROVAL DESIGN DEFECT
(As to GSK and Pfizer)

276. Plaintiff adopts, realleges, and incorporates by reference each allegation set forth in the preceding paragraphs as if fully stated herein.

277. GSK was the inventor of ranitidine and was the developer of prescription Zantac under NDA 18-709, 19-675, 20-095, and 20-251. GSK was also the developer of the various prescription and OTC Zantac products approved under NDAs 20-520 and 20-745, and all supplements. Pfizer was the developer of various OTC Zantac products approved under NDA 21-698 and all supplements.

278. NDAs 18-709, 19-675, 20-095, 20-251, 20-520, 20-745, and 21-698, and their respective supplements, were approved as new NDAs under section 505(b) of the FDCA.

279. GSK and Pfizer, as inventor and developers, knew or, by the exercise of reasonable care, should have known, ordinary consumers such as Plaintiff would not have realized the potential risks and dangers of Zantac.

280. At all relevant times, GSK and Pfizer had a duty to exercise reasonable care in the development, manufacture, supply, storage, transport, packaging, sale, and/or distribution of Zantac products, including the duty to take all reasonable steps necessary to manufacture, and/or sell a product that was not unreasonably dangerous to consumers and users of the product.

281. GSK's and Pfizer's duty of care owed to consumers, healthcare providers and the general public included providing accurate, true, and correct information concerning the risks of using Zantac, the risks of improper storage and exposure to heat and humidity, and appropriate, complete, and accurate warnings concerning the potential adverse effects of Zantac and, in particular, its ability to degrade into the carcinogenic compound NDMA under certain conditions.

282. At all relevant times before each of their respective NDAs were approved by the FDA, GSK and Pfizer knew or, in the exercise of reasonable care, should have known of the

hazards and dangers of Zantac and, specifically, the carcinogenic properties of NDMA when these products would be ingested by consumers, such as Plaintiff.

283. Accordingly, at all relevant times before the approval of their respective NDAs, GSK and Pfizer knew or, in the exercise of reasonable care, should have known that use of Zantac could cause the types of injuries suffered by Plaintiff herein, and thus, created a dangerous and unreasonable risk of injury to the users of these products. GSK and Pfizer also knew or, in the exercise of reasonable care, should have known that users and consumers would be unaware of the risks and the magnitude of the risks associated with use of Zantac.

284. As such, GSK and Pfizer breached their duty of reasonable care and failed to exercise ordinary care in the design, research, and development of Zantac products, in that GSK and Pfizer developed and produced defective Zantac which carries the potential to transform into the carcinogenic compound NDMA; knew or had reason to know of the defects inherent in their products; knew or had reason to know that a user's or consumer's storage and handling and use of the products created a significant risk of harm and unreasonably dangerous side effects; and failed to prevent or adequately warn of these risks and injuries.

285. Readily available testing methods revealed the dangers of GSK's and Pfizer's Zantac products. For example, gas chromatography-mass spectrometry, the technique Valisure employed in 2019 to identify NDMA forming in ranitidine, was a widely available, cost-effective, industry-standard testing method, developed and used to identify individual substances in a compound since 1955. If this testing method had been used by GSK and Pfizer to test ranitidine, as early as when GSK's predecessor first developed the ranitidine molecule, and certainly prior to the approval of all subsequent NDAs held by the GSK and Pfizer, they could have determined that ranitidine transform into NDMA under conditions likely to occur with the target market for

ranitidine.

286. GSK and Pfizer knew or should have known that ranitidine-containing products posed a grave risk of harm. The dangerous propensities of their products and the carcinogenic characteristics of NDMA as produced within the human body as a result of ingesting ranitidine, as described above, were known to GSK and Pfizer, or scientifically knowable to GSK and Pfizer through appropriate research and testing by known methods, at the time they sought approval from the FDA for their various respective NDAs for their Zantac products, but were not known to end users and consumers, including Plaintiff.

287. GSK and Pfizer owed a duty to all reasonably foreseeable users to design a safe product.

288. GSK and Pfizer breached their duty by failing to use reasonable care in the design of Zantac because the drug exposed users to unsafe levels of the carcinogen NDMA.

286. GSK and Pfizer breached their duty by failing to use reasonable care in the design of Zantac by negligently designing the drug with an inherent susceptibility to form NDMA. Alternative designs of the molecule—designs that were approved by the FDA—existed that substantially reduced the degradation of ranitidine into unsafe levels of NDMA.

287. GSK and Pfizer breached their duty by failing to use reasonable care in the design of their respective Zantac products before they were approved by the FDA:

a. Designing, developing, manufacturing, producing, formulating, creating, and/or distributing Zantac without thorough and adequate pre- and post-market testing;

b. Designing, developing, manufacturing, producing, formulating, creating, and/or distributing Zantac while negligently and/or intentionally concealing and failing to disclose the results of trials, tests, and studies of Zantac and the carcinogenic potential of NDMA as created in the human body as a result of ingesting Zantac, and, consequently, the risk of serious harm associated with human use of Zantac;

c. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not Zantac products were safe for their intended consumer use prior to the approval of their respective NDAs;

d. Failing to use reasonable and prudent care in testing, research, manufacture, storage, transport and development of Zantac products so as to avoid the risk of serious harm associated with the prevalent use of Zantac products;

e. Failing to design and manufacture Zantac so as to ensure it was at least as safe and effective as other medications on the market intended to treat the same symptoms;

f. Failing to provide adequate instructions, guidelines, and safety precautions to those persons GSK and Pfizer could reasonably foresee would use Zantac products;

g. Failing to disclose to Plaintiff, users/consumers, healthcare providers and the general public that use of Zantac presented significant risks of cancer and other grave illnesses;

h. Failing to warn Plaintiff, consumers, and the general public that the product's risk of harm was unreasonable and that there were safer and effective alternative medications available to Plaintiff and other consumers;

i. Systematically suppressing or downplaying contrary evidence about the risks, incidence, and prevalence of the side effects of Zantac products;

j. Representing that their products were safe for their intended use when, in fact, GSK and Pfizer knew or should have known the products were not safe for their intended purpose; and

k. Declining to make or propose appropriate product labeling or other promotional materials that would alert consumers and the general public of the risks.

289. GSK and Pfizer knew and/or should have known that foreseeable consumers, such as Plaintiff, would suffer injuries as a result of GSK's and Pfizer's failure to exercise ordinary care in the design, development, manufacturing, labeling, distribution, storage, transport, and sale of Zantac.

290. Plaintiff did not know the nature and extent of the injuries that could result from the intended use of and/or exposure to Zantac.

291. GSK's and Pfizer's negligence was the proximate cause of Plaintiff's injuries, i.e.,

absent GSK's and Pfizer's negligence, Plaintiff would not have developed cancer.

292. GSK's and Pfizer's conduct, as described above, was reckless and without regard for the safety of consumers including Plaintiff herein. GSK and Pfizer regularly risked the lives of consumers and users of their products, including Plaintiff, with full knowledge of the dangers of their products. GSK and Pfizer have made conscious decisions not to properly design, develop, and label their ranitidine products, including failing to propose a label for ranitidine that adequately informs the medical community and consumers of the risk of cancer as a result of NDMA contamination in ranitidine and failing to warn of appropriate conditions under which to store their products, the appropriate expiration dates, and the significant risks of seemingly harmless behavior such as storing ranitidine in a bathroom medicine cabinet where it would be regularly exposed to humidity.

293. GSK's and Pfizer's conduct as alleged herein was done with reckless disregard for human life, oppression, and malice. GSK and Pfizer were fully aware of the safety risks of Zantac, particularly its carcinogenic potential as it transforms into NDMA within the chemical environment of the human body and/or during transport and/or storage prior to the time their respective NDAs were approved by the FDA. Nonetheless, GSK and Pfizer deliberately crafted their label and warnings to mislead consumers. This was not done accidentally or through some justifiable negligence. Rather, GSK and Pfizer knew they could profit by convincing consumers that Zantac was harmless to humans, and that full disclosure of the true risks would limit the amount of money they would make selling the drugs. Their objective was accomplished not only through a misleading label, but through a comprehensive scheme of selective misleading research and testing, false advertising, and deceptive omissions as more fully alleged throughout this pleading. Plaintiff was denied the right to make an informed decision about whether to purchase

and use Zantac, knowing the full risks attendant to that use. Such conduct was done with conscious disregard of Plaintiff's rights.

294. GSK's and Pfizer's conduct, as described above, was willful, wanton, malicious, and conducted with reckless disregard for the health and safety of users of Zantac products, including Plaintiff.

295. As a direct and proximate result of GSK and Pfizer negligently placing defective Zantac products into the stream of commerce, Plaintiff suffered significant, serious, and permanent injury, and Plaintiff sustained pecuniary loss and general damages in a sum exceeding the jurisdictional minimum of this Court.

296. As a proximate result of GSK and Pfizer negligently placing defective Zantac products into the stream of commerce, as alleged herein, there was a measurable and significant interval of time during which Plaintiff suffered great mental anguish, personal injury, and other damages.

297. As a proximate result of GSK and Pfizer negligently placing defective Zantac products into the stream of commerce, as alleged herein, Plaintiff suffered injuries, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to, past and future medical expenses, lost income, and other damages.

298. As a proximate result of GSK and Pfizer negligently placing defective Zantac products into the stream of commerce, as alleged herein, there was a measurable and significant interval of time during which Plaintiff suffered great mental anguish, personal injury, and other damages.

299. As a proximate result of GSK and Pfizer negligently placing defective Zantac

products into the stream of commerce, as alleged herein, Plaintiff suffered injuries, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to, past and future medical expenses, lost income, and other damages.

COUNT III
STRICT LIABILITY – FAILURE TO WARN
(As to Brand Defendants)

300. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

301. At all relevant times, Brand Defendants engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and/or promoting ranitidine-containing products, which are defective and unreasonably dangerous to consumers; including Plaintiff, because they do not contain adequate warnings or instructions concerning the proper expiration date of the product nor the dangerous characteristics of ranitidine and NDMA. These actions were under the ultimate control and supervision of Brand Defendants.

302. Brand Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, stored, transported, sold, and/or otherwise released into the stream of commerce Zantac products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiff, and therefore had a continuing duty to warn of the risks associated with the use of Zantac products.

303. Brand Defendants also had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as the packaging, storage and handling or ranitidine.

304. Brand Defendants, as a manufacturer and seller of pharmaceutical medications, are held to the knowledge of an expert in the field.

305. At the time of manufacture, Brand Defendants could have provided warnings or instructions regarding the full and complete risks of ranitidine-containing products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products.

306. At various points in time, Brand Defendants possessed new information or new analyses of existing information that empowered them unilaterally to change the warnings and precautions section of their Zantac products' label.

307. At all relevant times, Brand Defendants failed and deliberately refused to investigate, study, test, promote the safety of, or minimize the dangers to users and consumers of their ranitidine-containing products and to those who would foreseeably use or be harmed by Brand Defendants' Zantac products, including Plaintiff.

308. Even though Brand Defendants knew or should have known that ranitidine posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure. The dangerous propensities of their products and the carcinogenic characteristics of NDMA as produced within the human body as a result of ingesting ranitidine, as described above, were known to Brand Defendants, or scientifically knowable to Brand Defendants through appropriate research and testing by known methods, at the time they manufactured, distributed, supplied or sold the product, and were not known to end users and consumers, such as Plaintiff.

309. To mitigate degradation of ranitidine into NDMA over time, and in the presence of heat or humidity, consumers should have been warned to consume ranitidine shortly after manufacturing. No ranitidine-containing product contained this warning.

310. In fact, ranitidine-containing products had expiration dating periods of one or two

years allowing accumulation of more and more unsafe levels of NDMA. A much shorter period of a matter of months would have ensured that ranitidine contained far lower levels of NDMA when consumed.

311. In setting expiration and/or retest dates for their ranitidine-containing drugs, Brand Defendants were required to take into consideration the real-world conditions the drugs would be exposed to, including the conditions under which the drugs would be stored and shipped. See 21 C.F.R. § 211.137.

312. In setting expiration and/or retest dates for their ranitidine-containing drugs, Brand Defendants were required to base those dates on stability testing, which in turn must account for storage conditions. 21 C.F.R. § 211.166.

313. Brand Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein, and Brand Defendants failed to adequately warn consumers (i.e., the reasonably foreseeable users) of the risks of exposure to their products. Brand Defendants have wrongfully concealed information concerning the dangerous nature of ranitidine-containing products, the potential for ingested ranitidine to transform into the carcinogenic NDMA compound, and further, have made false and/or misleading statements concerning the safety of ranitidine-containing products.

314. At all relevant times, Brand Defendants' Zantac products reached the intended consumers, handlers, and users, or other persons coming into contact with these products within this State and throughout the United States, including Plaintiff, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Brand Defendants.

315. Plaintiff was exposed to Brand Defendants' Zantac products without knowledge of

their dangerous characteristics.

316. At all relevant times, Plaintiff used Brand Defendants' Zantac products for their intended or reasonably foreseeable purposes, without knowledge of their dangerous characteristics.

317. Plaintiff did not discover and could not have reasonably discovered the defects and risks associated with ranitidine-containing products prior to or at the time of Plaintiff consuming them. Plaintiff relied upon the skill, superior knowledge, and judgment of Brand Defendants to know about and disclose serious health risks associated with using Brand Defendants' products.

318. Brand Defendants knew or should have known that the minimal warnings disseminated with their ranitidine-containing products were inadequate, failed to communicate adequate information on the dangers and safe use/exposure, and failed to communicate warnings and instructions that were appropriate and adequate to render the products safe for their ordinary, intended, and reasonably foreseeable uses.

319. The information that Brand Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiff to utilize the products safely and with adequate protection. Instead, Brand Defendants: disseminated information that was inaccurate, false, and misleading; failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with use of and/or exposure to ranitidine; continued to aggressively promote the efficacy of their products, even after they knew or should have known of the unreasonable risks from use or exposure; and concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting ranitidine-containing products.

320. This alleged failure to warn is not limited to the information contained on Zantac's labeling. The Brand Defendants should have disclosed the known risks associated with Zantac and ranitidine-containing products through other non-labeling mediums (i.e., promotion, advertisements, public service announcements, and/or public information sources), but the Brand Defendants did not disclose these known risks through any medium.

321. Brand Defendants are liable to Plaintiff for injuries caused by their negligent, willful or reckless conduct, as described above. Brand Defendants risked the lives of consumers and users of their products, including Plaintiff, by consciously deciding not to warn or inform physicians, patients and the public of known safety problems associated with ranitidine-containing products.

322. Had Brand Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their ranitidine-containing products, Plaintiff could have avoided the risk of developing injuries and could have obtained or used alternative medication.

323. As a direct and proximate result of Brand Defendants placing their defective Zantac products into the stream of commerce, and the resulting injuries, Plaintiff sustained personal injuries, mental anguish, loss of income, loss of earning capacity, pecuniary loss, and other damages which exceeds the jurisdictional minimum of this Court.

COUNT IV
NEGLIGENCE – FAILURE TO WARN
(Against All Brand Defendants)

324. Plaintiff incorporates by reference each allegation set forth in the preceding paragraphs as if fully stated herein.

325. Ranitidine leads to NDMA exposure in the following ways: (1) the NDMA levels

in ranitidine increase as the drug breaks down in the human digestive system and interacts with various enzymes in the human body; (2) the ranitidine molecule internally degrades to form NDMA, and the NDMA levels in the drug substance and the drug product increase over time under normal storage conditions, but more so with exposure to heat or humidity.

326. NDMA is a potent carcinogen in humans. Higher exposure to NDMA over longer time periods leads to even higher risks of cancer.

327. To mitigate degradation of ranitidine into NDMA in the stomach, over time, and in the presence of heat or humidity, consumers could be warned:

a. To consume ranitidine shortly after manufacturing and to store it in a cool, dry place (e.g., not in a bathroom). No ranitidine containing product contained this warning.

b. To consume ranitidine for only short periods of time. No ranitidine-containing product warned that cancer could result from long-term ingestion of ranitidine.

c. Not to take ranitidine with or after meals or in combination with a high-nitrite diet. No ranitidine-containing product contained this warning.

d. To take ranitidine with Vitamin E or Vitamin C to inhibit nitrosation and the formation of NDMA in the stomach. No ranitidine-containing product contained this warning.

328. To mitigate degradation of ranitidine into NDMA over time, and in the presence of heat or humidity, consumers should have been warned to consume Zantac shortly after manufacturing. No Zantac product contained this warning.

329. In fact, Zantac products had expiration dating periods of one or two years allowing accumulation of more and more unsafe levels of NDMA. A much shorter period of a matter of months would have ensured that ranitidine contained far lower levels of NDMA when consumed.

330. In setting expiration and/or retest dates for their ranitidine-containing drugs, Brand Defendants were required to take into consideration the real-world conditions the drugs would be

exposed to, including the conditions under which the drugs would be stored and shipped. See 21 C.F.R. § 211.137.

331. A manufacturer has a duty of reasonable care to provide an adequate warning about known risks. The risk posed from NDMA in Zantac was known and/or knowable by Brand Defendants. Brand Defendants' duty of care owed to consumers and the general public included the duty to provide accurate, true, and correct information concerning the risks of using ranitidine-containing products and appropriate, complete, and accurate warnings concerning the potential adverse effects of ranitidine-containing products and, in particular, its ability to transform into the carcinogenic compound NDMA. Brand Defendants had a continuing duty to provide appropriate and accurate warnings and precautions.

332. Brand Defendants, as manufacturers and sellers of pharmaceutical medication, are held to the knowledge of an expert in the field.

333. At all relevant times, Brand Defendants negligently designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold ranitidine-containing products, which are defective and unreasonably dangerous to consumers, including Plaintiff, because they do not contain adequate warnings concerning the dangerous characteristics of Zantac and NDMA. These actions were under the ultimate control and supervision of Brand Defendants as holders of the various Zantac NDAs.

334. At all relevant times, Brand Defendants knew or, in the exercise of reasonable care, should have known of the hazards and dangers of ranitidine-containing products and, specifically, the carcinogenic properties of NDMA when ranitidine is ingested. Brand Defendants knew or should have known about each of these risks in time to warn consumers.

335. Even though Brand Defendants knew or should have known that Zantac posed a

grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to ranitidine-containing products. The dangerous propensities of ranitidine-containing products and the carcinogenic characteristics of NDMA, as described above, were known to Brand Defendants, or scientifically knowable to Brand Defendants through appropriate research and testing by known methods, at the time they manufactured, marketed, distributed, supplied, or sold the products, but were not known to end users and consumers, including Plaintiff.

336. Brand Defendants negligently failed to warn and have wrongfully concealed information concerning the dangerous level of NDMA in ranitidine-containing products, and further, have made false and/or misleading statements concerning the safety of Zantac.

337. At the time of manufacture, Brand Defendants could have provided warnings or instructions regarding the full and complete risks of Zantac because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products.

338. At various points in time, Brand Defendants possessed new information or new analyses of existing information that empowered them unilaterally to change the warnings and precautions section of their Zantac products' label.

339. At all relevant times, Brand Defendants negligently failed and deliberately refused to investigate, study, test, or promote the safety or to minimize the dangers to users and consumers of their products and to those who would foreseeably use or be harmed by Zantac.

340. Each individual Brand Defendant breached this duty for the Zantac products it manufactured, marketed, and sold. The warnings included on each ranitidine-containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored or transported under humid conditions, when stored or transported under

hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture. Plaintiff and/or Plaintiff's doctors would have read and heeded these warnings. As a result, Plaintiff would not have ingested Zantac and would not have developed cancer or otherwise been harmed by exposure to NDMA in these products.

341. Despite this ability, Brand Defendants failed to warn of the risks of NDMA in the warnings and precautions section of their Zantac products' label.

342. Plaintiff was exposed to Brand Defendants' Zantac products without knowledge of their dangerous characteristics. Plaintiff could not have reasonably discovered the risks associated with ranitidine-containing products prior to or at the time Plaintiff consumed the drugs. Plaintiff and Plaintiff's physicians relied upon the skill, superior knowledge, and judgment of Brand Defendants to know about and disclose serious health risks associated with using Brand Defendants' products.

343. At all relevant times, Plaintiff used and/or was exposed to Brand Defendants' Zantac products while using them for their intended or reasonably foreseeable purposes, without knowledge of their dangerous characteristics.

344. Brand Defendants knew or should have known that the minimal warnings disseminated with their Zantac products were inadequate, failed to communicate adequate information on the dangers and safe use/exposure, and failed to communicate warnings and instructions that were appropriate and adequate to render the products safe for their ordinary, intended and reasonably foreseeable uses. The information that Brand Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiff to avoid using the drug. Instead, Brand Defendants disseminated information that was inaccurate, false, and misleading, and which failed to

communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with use of and/or exposure to ranitidine; continued to aggressively promote the efficacy of ranitidine-containing products, even after they knew or should have known of the unreasonable risks from use or exposure; and concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Zantac.

345. Had Brand Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Zantac products on the warnings and precautions section of their products' labels, Plaintiff could have avoided the risk of developing cancer and could have obtained or used alternative medication. However, as a result of Brand Defendants' concealment of the dangers posed by their Zantac products, Plaintiff was not alerted, and so could not avert Plaintiff's injuries.

346. Brand Defendants' conduct, as described above, was reckless.

347. Brand Defendants risked the lives of consumers and users of their products, including Plaintiff, with knowledge of the safety problems associated with ranitidine-containing products and suppressed this knowledge from the public. Brand Defendants made conscious decisions not to warn or inform the unsuspecting public. Brand Defendants' reckless conduct warrants an award of punitive damages.

348. Brand Defendants' lack of adequate warnings and instructions in the warnings and precautions section of their Zantac products' labels were a substantial factor in causing Plaintiff's injuries.

349. As a direct and proximate result of Brand Defendants' failure to provide an adequate warning of the risks of ranitidine-containing products, Plaintiff suffered injuries,

sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to, past and future medical expenses, lost income, and other damages.

COUNT V
CIVIL CONSPIRACY
(As to Brand Defendants)

350. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

351. Brand Defendants and/or their predecessors-in-interest knowingly and voluntarily agreed, contrived, combined, confederated, and conspired among themselves to cause Plaintiff injuries, disease, and/or illnesses by exposing Plaintiff to harmful and dangerous Zantac products.

352. Brand Defendants further knowingly and voluntarily agreed, contrived, confederated, and conspired to withhold from consumers such as Plaintiff scientific data, adequate labeling, and proper warnings regarding the risk of cancer associated with their NDMA-contaminated Zantac products.

353. Defendants GSK and Pfizer entered into an agreement in 1993 to develop OTC Zantac, which resulted the formulation of the drug, and the withholding of known risks of NDMA contamination, submitted to the FDA for approval in NDA 20-520.

354. All Brand Defendants agreed to withhold from the public known information about NDMA contamination of their respective Zantac products and the resultant increased risk of cancer in their packaging, branding, labeling, advertising, promotional, and marketing activities.

355. The agreements among the Brand Defendants were in contravention of federal and state laws regarding the misbranding of drugs, sale of defective products, and post-approval reporting, including:

a. The Food, Drug, and Cosmetic Act, 21 U.S.C. § 355, et seq., which requires that companies filing an application for a new NDA for approval submit, *inter alia*, "full reports of investigations which have been made to show whether such drug is safe for use and whether such drug is effective in use." 21 U.S.C. § 355(b)(1)(A)(i);

b. The Food, Drug, and Cosmetic Act, 21 U.S.C. § 352 which declares a drug to be misbranded if the label "is false or misleading in any particular," 21 U.S.C. §352(a)(1), and further requires the label to include "(1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users." *Id.* at § 352(f). Furthermore, a drug can be misbranded if it is deteriorative and the label fails to contain a statement of such precautions. *Id.* at 352(h).

c. FDA Regulations, 21 C.F.R. Part 314, which require, *inter alia*, the following post-marketing reports:

1. A brief summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product, along with a report of the steps the NDA applicant intends to take as a result of this information, including adding a warning to the label. 21 C.F.R. § 314.81(b)(2)(i).

2. A report of "experiences, investigations, studies, or tests involving chemical or physical properties, or any other properties of the drug (such as the drug's behavior or properties in relation to microorganisms, including both the effects of the drug on microorganisms and the effects of microorganisms on the drug). These reports are only required for new information that may affect FDA's previous conclusions about the safety or effectiveness of the drug product." 21 C.F.R. § 314.81(b)(2)(iv).

3. Copies of unpublished reports and summaries of published reports of new toxicological findings in animal studies and in vitro studies (e.g., mutagenicity) conducted by, or otherwise obtained by, the applicant concerning the ingredients in the drug product. 21 C.F.R. § 314.81(b)(2)(v).

4. Published clinical trials of the drug (or abstracts of them), including clinical trials on safety and effectiveness; clinical trials on new uses; biopharmaceutic, pharmacokinetic, and clinical pharmacology studies; and reports of clinical experience pertinent to safety (for example, epidemiologic studies or analyses of experience in a

monitored series of patients) conducted by or otherwise obtained by the applicant. 21 C.F.R. § 314.81(b)(2)(vi); and

d. Parallel Illinois state laws that prohibit the dissemination of misbranded drugs, including 410 ILCS § 620/15 which parallels 21 C.F.R. § 314.81(b)(2)(i) and 21 U.S.C. §§ 352(a)(1), 352(f) and 352(h).

353. In furtherance of these agreements, the Brand Defendants committed the following tortious acts:

a. Defendant GSK withheld the scientific literature of which it was aware related to the risk of developing cancer as a result of taking NDMA contaminated ranitidine, and further issued labels without any warnings related to the presence of NDMA and the resultant increased risk of developing cancer in the labeling of Zantac during the times they developed, packaged, branded, labeled, advertised, promoted, and marketed their Zantac products, which forms the basis of Counts III and IV herein;

b. Defendant Pfizer withheld the scientific literature of which it was aware related to the risk of developing cancer as a result of taking NDMA contaminated ranitidine, and further issued labels without any warnings related to the presence of NDMA and the resultant increased risk of developing cancer in the labeling of Zantac during the times they developed, packaged, branded, labeled, advertised, promoted, and marketed their Zantac products, which forms the basis of Counts III and IV herein; and

c. Defendant Boehringer Ingelheim withheld the scientific literature of which it was aware related to the risk of developing cancer as a result of taking NDMA contaminated ranitidine, and further issued labels without any warnings related to the presence of NDMA and the resultant increased risk of developing cancer in the labeling of OTC Zantac during the times they developed, packaged, branded, labeled, advertised, promoted, and marketed their Zantac products, which forms the basis of Counts III and IV herein; and

354. As a direct and proximate result of Brand Defendants' tortious acts in furtherance of this conspiracy, Plaintiff suffered injuries, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to, past and future medical expenses, lost income, and other damages.

COUNT VI

NEGLIGENT STORAGE AND TRANSPORTATION
(As to All Defendants)

355. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

356. As previously alleged, ranitidine degrades into NDMA more quickly at higher temperatures, at higher humidity levels, and under other poor storage or handling conditions.

357. Defendants were aware of the need to maintain sensitive pharmaceutical drugs under proper shipping and storage conditions, and that maintaining the highest safety techniques is best for the consumer. Pharmaceutical companies are well aware of the importance of precise temperature control down to the degree, and advertise on their ability to provide precise, quality service. More precise, colder transportation is, of course, more expensive than less precise, warmer transportation.

358. Testing of the quantity of NDMA in ranitidine performed to date has shown substantial variation among different batches. Some ranitidine has significantly more NDMA when tested.

359. NDMA forms due to chemical reactions in the human body, and also from degradation before consumption (principally heat, humidity, or time). Testing is performed before consumption and the age of the ranitidine is documented, so neither time nor degradation in the body should produce substantial variation. The best inference must be that substantial variation in heat and humidity is causing differing amounts of NDMA to form.

360. Different ranitidine-containing products listed slightly different storage and transportation requirements.

361. Defendants systematically exposed Zantac to excessive levels of heat and humidity that violated the instructions on the products' labels.

362. Defendants failed to implement rigorous policies to ensure substantial compliance with the heat and humidity requirements on product labels. This failure led to widespread noncompliance.

363. For example, Defendants shipped ranitidine-containing products through the mail. This method of transportation—whether through the United States Postal Service or large common carriers such as FedEx and UPS—does not guarantee controlled temperature or humidity. Because of Defendants' choice to use or allow this method of transportation, ranitidine-containing products shipped through the mail were systematically subject to excessive heat or humidity on days when the weather was hot or humid.

364. Defendants, directly or indirectly, transported, stored, handled, and/or sold Zantac products that were used by Plaintiff.

365. At all relevant times, Defendants, had a duty to exercise reasonable care in the storage and transportation of ranitidine-containing products to ensure the products were not unreasonably dangerous to consumers and users.

366. Defendants breached this duty by failing to implement or enforce policies to ensure Zantac products remained free from excessive heat and humidity, as required both by the duty of reasonable care and the label.

367. At all relevant times, Defendants knew or should have known of the need for storing and transporting Zantac products within the labeled temperature range and at low humidity. Yet, Defendants ignored this risk. They did not ensure Zantac products were stored at low humidity or within the temperature range on the label. Instead, some Zantac was subjected to excessive humidity and heat during storage, transportation, and shipping which caused the drug to degrade leading to the formation of excessive levels of NDMA.

368. Ignoring the risks of NDMA forming was unreasonable and reckless.

369. Plaintiff did not know the nature and extent of the injuries that could result from the intended use of and/or exposure to ranitidine-containing products.

370. Defendants' negligence was a substantial factor in causing Plaintiff's injuries.

371. As a direct and proximate result of Defendants' failure to store and transport Zantac products properly, Plaintiff has suffered injuries, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, and other damages.

372. As a direct and proximate result of these systematic failures, excessive levels of NDMA formed in the Zantac products the Defendants handled, stored and sold. These high levels of NDMA caused Plaintiff's injuries.

COUNT VIII
NEGLIGENT MISREPRESENTATION
(As to All Defendants)

373. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

374. The brand name Zantac ranitidine-containing products complained of were designed, manufactured, advertised, marketed, distributed, and/or sold by the Defendants, which Plaintiff regularly used and ingested.

375. At all relevant times, and in their relevant capacities described above, Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold their Zantac products, which are defective and unreasonably dangerous to consumers, including Plaintiff, because Zantac products do not contain adequate warnings or instructions concerning the dangerous characteristics of ranitidine and NDMA. These actions were under the ultimate control and supervision of the Defendants.

376. Defendants represented directly to consumers, including Plaintiff, via the media, advertising, website, social media, packaging, and promotions, among other misrepresentations and omissions described herein that:

a. the Zantac products were both safe and effective for the lifetime of the product, when in fact, the drug contains unsafe levels of NDMA far in excess of the 96ng limit that increases at various points during the shipping, handling, storage, and consumption phases and as the product ages;

b. consumption of Zantac would not result in excessive amounts of NDMA being formed in their bodies;

c. the levels of NDMA in Zantac have no practical clinical significance; and

d. Zantac products were safe for their intended use when, in fact, Defendants knew or should have known the products were not safe for their intended purpose.

377. These representations were false. Because of the unsafe levels of NDMA in Zantac products, the drug presented an unacceptable risk of causing cancer. These products are so unsafe that the FDA was compelled to order the immediate withdrawal of all ranitidine-containing products on April 1, 2020.

378. Defendants knew that their ranitidine-containing products would be used by their customers, such as Plaintiff, without inspection for defects and that any such inspection would not have advised Plaintiff of the fact that these products could cause the injuries which Plaintiff suffered. Such facts made the Defendants' Zantac products inherently and unreasonably dangerous in that Plaintiff was not apprised of, could not and would not contemplate the danger and/or the extent of the danger of contracting cancer and the associated injuries and complications as a result of their exposure to ranitidine and NDMA.

379. Defendants knew or should have known these representations were false and negligently made them without regard for their truth.

380. Defendants had a duty to accurately provide this information to Plaintiff. In

concealing this information from Plaintiff, Defendants breached their duty. Defendants also gained financially from, and as a result of their breach.

381. Defendants intended for Plaintiff and/or Plaintiff's physician(s) to rely on these representations.

382. Each of these misrepresentations were material at the time they were made. In particular, each of the misrepresentations concerned material facts that were essential to the analysis undertaken by Plaintiff as to whether to purchase or consume Zantac products.

383. Plaintiff relied on the Defendants' statements regarding their Zantac products by using and ingesting the these in the manner in which they were intended or reasonably foreseeable to the Defendants.

384. Plaintiff would not have regularly used and ingested these Zantac products if Defendants did not make the foregoing misrepresentations.

385. Defendants' acts and omissions as described herein were committed in reckless disregard of Plaintiff's rights, interests, and well-being to enrich Defendants.

386. Each of the Defendants owed a duty to Plaintiff and the general public to make accurate and truthful representations regarding their Zantac products, and the Defendants breached their duty, thereby causing Plaintiff to suffer harm.

387. Plaintiff was exposed to the Defendants' ranitidine-containing products whenever Plaintiff took them. Each exposure to Defendants' ranitidine-containing products caused Plaintiff to be exposed to additional and accumulating NDMA, which then resulted in and directly caused Plaintiff to suffer severe bodily injuries, specifically cancer. Each exposure to these products was harmful and caused or contributed substantially to Plaintiff's injuries.

388. As a direct and proximate result of the Defendants' negligent misrepresentations

concerning their Zantac products, Plaintiff has suffered injuries, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, and other damages.

COUNT IX
BREACH OF EXPRESS WARRANTIES
(As to All Defendants)

389. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

390. The brand name Zantac ranitidine-containing products complained of were designed, manufactured, advertised, marketed, distributed, and/or sold by the Defendants, which Plaintiff regularly used and ingested.

391. At all relevant times, Defendants engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and/or promoting ranitidine-containing Zantac products, which are defective and unreasonably dangerous to consumers, including Plaintiff, thereby placing Zantac products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants.

392. Defendants had a duty to exercise reasonable care in the research, development, design, testing, packaging, manufacture, inspection, labeling, distributing, marketing, promotion, sale, and release of Zantac products, including a duty to:

a. ensure that their products did not cause the user unreasonably dangerous side effects;

b. warn of dangerous and potentially fatal side effects;

c. disclose adverse material facts, such as the true risks associated with the use of and exposure to ranitidine, when making representations to the FDA, consumers and the general public, including Plaintiff; and

d. set proper expiration dates and storage temperatures and disclose the adverse consequences should ranitidine not be stored properly.

393. As alleged throughout this pleading, the ability of Defendants to properly disclose those risks associated with its drugs are not limited to representations made on the labeling.

394. At all relevant times, Defendants expressly represented and warranted to the purchasers of their products, including Plaintiff, by and through statements made by Defendants in labels, publications, package inserts, and other written materials intended for consumers and the general public, that ranitidine-containing products were safe to human health and the environment, effective, fit, and proper for their intended use. Defendants advertised, labeled, marketed, and promoted its products, representing the quality to consumers and the public in such a way as to induce their purchase or use, thereby making an express warranty that its ranitidine-containing products would conform to the representations.

395. These express representations include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to ranitidine. Defendants knew and/or should have known that the risks expressly included in the warnings and labels did not and do not accurately or adequately set forth the risks of developing the serious injuries complained of herein. Nevertheless, Defendants expressly represented that its ranitidine tablets were safe and effective, that it was safe and effective for use by individuals such as Plaintiff, and/or that it was safe and effective as consumer medication.

396. The representations about Zantac products, as set forth herein, contained or constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, creating an express warranty that the goods would conform to the representations.

397. Plaintiff purchased Zantac products directly at Walgreens retail locations.

398. Plaintiff is a third-party beneficiaries of the various contracts that Defendants

entered into for the distribution and retail sale of their Zantac products.

399. Defendants placed Zantac tablets into the stream of commerce for sale and recommended its use to consumers and the public without adequately warning of the true risks of developing the injuries associated with the ingestion of improperly stored ranitidine.

400. Defendants breached these warranties because, among other things, Zantac products were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose.

401. Specifically, Defendants breached the warranties in the following ways:

a. Defendants represented through their labeling, advertising, and marketing materials that its products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with improper storage and handling of use ranitidine; and

b. Defendants represented that its products were safe for use and intentionally concealed information that demonstrated that ranitidine, by transforming into NDMA when improperly stored or handled, had carcinogenic properties, and that its products, therefore, were not safer than alternatives available on the market.

402. Plaintiff detrimentally relied on the express warranties and representations of Defendants concerning the safety and/or risk profile of ranitidine in deciding to purchase the product. Plaintiff reasonably relied upon Defendants to disclose known defects, risks, dangers, and side effects of its products if not stored, shipped and handled properly. Plaintiff would not have purchased Zantac had Defendants properly disclosed the risks associated with the products, either through advertising, labeling, or any other form of disclosure.

403. Defendants had sole access to material facts concerning the nature of the risks associated with their products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiff could not have reasonably discovered that the risks expressly

included in its warnings and labels were inadequate and inaccurate.

404. Plaintiff had no knowledge of, and could not reasonably have discovered, the falsity or incompleteness of Defendants' statements and representations concerning Zantac.

405. Plaintiff used and/or were exposed to Zantac as manufactured, tested, inspected, labeled, distributed, packaged, marketed, promoted, sold, or otherwise released into the stream of commerce by Defendants.

406. Had the labels, advertisements, or promotional material for its products accurately and adequately set forth the true risks associated with the use of such products, including Plaintiff's injuries, rather than expressly excluding such information and warranting that the products were safe for their intended use, Plaintiff could have avoided the injuries complained of herein.

407. As a direct and proximate result of Defendants' breach of express warranty, Plaintiff has sustained pecuniary loss and general damages in a sum exceeding the jurisdictional minimum of this Court.

408. As a proximate result of Defendants' breach of express warranty, as alleged herein, there was a measurable and significant interval of time during which Plaintiff suffered great mental anguish and other personal injury and damages.

409. As a proximate result of Defendants' breach of express warranty, as alleged herein, Plaintiff has suffered injuries, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, and other damages.

COUNT X
BREACH OF IMPLIED WARRANTIES
(As to All Defendants)

410. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

411. This Count alleges a claim by Plaintiff for Zantac Plaintiff consumed and that each Defendant manufactured or sold.

412. At all relevant times, Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold Zantac products, which were and are defective and unreasonably dangerous to consumers, including Plaintiff, thereby placing Zantac products into the stream of commerce.

413. Before the time Plaintiff used Zantac products, Defendants impliedly warranted to their consumers, including Plaintiff, that ranitidine-containing products were of merchantable quality and safe and fit for the use for which they were intended; specifically, as consumer medication.

414. Zantac was not merchantable, not safe, and not fit for its use as a consumer medication because it degraded into NDMA, a potent carcinogen. By selling Zantac despite these flaws, Defendants breached their implied warranties.

415. Plaintiff purchased Zantac products directly at Walgreens retail locations.

416. Plaintiff is a third-party beneficiary of the various contracts that Brand Defendants entered into for the distribution and retail sale of their Zantac products.

417. At all relevant times, Defendants were aware that consumers and users of their products, including Plaintiff, would use Zantac products as marketed by Defendants, which is to say that Plaintiff was a foreseeable user of Zantac products.

418. Defendants intended that Zantac products be used in the manner in which Plaintiff, in fact, used them and which Defendants impliedly warranted to be of merchantable quality, safe, and fit for this use, even though Zantac products were not safe because they degraded into NDMA.

419. In reliance upon Defendants' implied warranty, Plaintiff used Zantac products as

instructed and labeled and in the foreseeable manner intended, recommended, promoted, and marketed by Defendants.

420. Plaintiff could not have reasonably discovered or known of the risks of serious injury associated with Zantac products.

421. The harm caused by Defendants' ranitidine-containing products far outweighed their benefit, rendering the products more dangerous than an ordinary consumer or user would expect and more dangerous than alternative products.

422. Defendants' breach of these implied warranties was a substantial factor is causing Plaintiff's harm described herein, including personal injuries.

423. As a proximate result of Defendants' breach of express warranty, as alleged herein, Plaintiff has suffered injuries, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, and other damages.

COUNT XI
COMMON LAW FRAUD
(As to All Defendants)

424. Plaintiff incorporates by reference every and every allegation of this Complaint as if fully stated herein.

425. Defendants intentionally and/or with reckless disregard for the truth misrepresented to Plaintiff material facts regarding the safety and effectiveness of Zantac.

426. Defendants knew or recklessly disregarded the fact that these representations were false, yet made the deceitful representations to Plaintiff.

427. Defendants actively concealed and intentionally omitted material facts about the defects and dangers of ranitidine for the purpose that Plaintiff and the consuming public would rely on such information, or the absence of information, in selecting Zantac as a treatment.

428. The maker's knowledge of the falsity of the representation fundamentally supplies the element of "fraudulent utterance" required to make a misrepresentation actionable.

429. Defendants made the misrepresentations and omissions of material facts alleged herein with the intent to induce consumers, like Plaintiff, to take their Zantac products.

430. As a result of these false and deceitful representations and omissions made by Defendants, which Defendants knew to be untrue or for which Defendants recklessly disregarded the truth, Plaintiff in fact relied on such misrepresentations and omissions by purchasing and ingesting Defendants' Zantac products, thus causing the significant injuries and harm described herein.

431. As a direct and proximate result of the foregoing misrepresentations omissions, and deceitful intentions, Plaintiff sustained serious injuries of a personal and pecuniary nature. Plaintiff suffered serious injuries, including cancer and permanent disability and disfigurement. As a direct and proximate result of the foregoing misrepresentations, omissions, and deceitful intentions, Plaintiff requires and/or will require more healthcare and services and did incur medical, health, incidental, and related expenses. Plaintiff will also require additional medical and/or hospital care, attention, and services in the future.

COUNT XII
ILLINOIS CONSUMER FRAUD ACT
(As to All Defendants)

432. Plaintiff incorporates by reference every and every allegation of this Complaint as if fully stated herein.

433. Defendants intentionally and/or with reckless disregard for the truth misrepresented to Plaintiff material facts regarding the safety and effectiveness of Zantac.

434. Defendants knew or recklessly disregarded the fact that these representations were false, yet made the deceitful representations to Plaintiff.

435. Defendants actively concealed and intentionally omitted material facts about the defects and dangers of ranitidine for the purpose that Plaintiff and the consuming public would rely on such information, or the absence of information, in selecting Zantac as a treatment.

436. The Defendants' intentional material misrepresentations and omissions as described fully in this Complaint constitute deceptive acts or practices under the Illinois Consumer Fraud Act.

437. The Defendants engaged in these deceptive acts or practices with the intent that Plaintiff would rely on the deceptions.

438. Defendants made the misrepresentations and omissions of material facts alleged herein with the intent to induce consumers, like Plaintiff, to purchase their ranitidine-containing Zantac products.

439. The deceptions committed by Defendants as described herein occurred in the course of conduct involving trade and commerce, i.e., Defendants made such material misrepresentations and omissions as an inducement for Plaintiff and other consumers to purchase their products in the stream of commerce, from which Defendants collectively earned billions of dollars from the sales of ranitidine-containing Zantac products.

440. As a result of these false and deceitful representations and omissions made by Defendants, which Defendants knew to be untrue or for which Defendants recklessly disregarded the truth, Plaintiff in fact relied on such misrepresentations and omissions by purchasing and ingesting Defendants' Zantac products, thus causing the significant injuries and harm described herein.

441. As a direct and proximate result of the foregoing misrepresentations omissions, and deceitful intentions, Plaintiff sustained serious injuries of a personal and pecuniary nature.

Plaintiff suffered serious injuries, including cancer and permanent disability and disfigurement. As a direct and proximate result of the foregoing misrepresentations, omissions, and deceitful intentions, Plaintiff requires and/or will require more healthcare and services and did incur medical, health, incidental, and related expenses. Plaintiff will also require additional medical and/or hospital care, attention, and services in the future.

JURY TRIAL DEMAND

Pursuant to 735 ILCS 5/2-1105, Plaintiff hereby demands a trial by jury on all the triable issues within this pleading.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests the Court to enter judgment in Plaintiff's favor and against Defendants for:

a. actual or compensatory damages in such amount to be determined at trial and as provided by applicable law;

b. pre-judgment and post-judgment interest;

c. reasonable attorneys' fees as provided by law;

d. costs and expenses of these actions;

e. statutory damages, treble damages and other relief permitted by the laws of the states that will govern these actions; and

f. any other relief the Court may deem just and proper.

DATED: August 8, 2023

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that the foregoing was furnished via email to the below named counsel on this 8th day of August, 2023:

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